TRIANGLE PHARMACEUTICALS INC
Form 10-K405
March 25, 2002

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 fiscal year ended December 31, 2001

OR

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

For the transition period from _____ to _____.

Commission File Number: 000-21589

TRIANGLE PHARMACEUTICALS, INC.
(Exact name of Registrant as specified in its charter)

| DELAWARE | 56-1930728 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

4 University Place, 4611 University Drive, Durham, North Carolina 27707
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: (919) 493-5980

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant as of January 31, 2002, was approximately $158 million. For the purposes of this calculation, shares owned by officers, directors and 10% stockholders known to the registrant have been excluded. Such exclusion is not intended, nor shall it be deemed, to be an admission that such persons are affiliates of the registrant.

The number of shares of the registrant's Common Stock outstanding as of January 31, 2002, was 76,828,854.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for the 2002 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference as provided in Part III of this Annual Report on Form 10-K.



## PART I

### ITEM 1. BUSINESS

THIS ANNUAL REPORT ON FORM 10-K MAY CONTAIN PROJECTIONS, ESTIMATES AND OTHER FORWARD-LOOKING STATEMENTS THAT INVOLVE A NUMBER OF RISKS AND UNCERTAINTIES, INCLUDING THOSE DISCUSSED BELOW AT "RISK AND UNCERTAINTIES." WHILE THIS OUTLOOK REPRESENTS OUR CURRENT JUDGMENT ON THE FUTURE DIRECTION OF THE BUSINESS, SUCH RISK AND UNCERTAINTIES COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM ANY FUTURE PERFORMANCE SUGGESTED BELOW. WE UNDERTAKE NO OBLIGATION TO RELEASE PUBLICLY THE RESULTS OF ANY REVISIONS TO THESE FORWARD-LOOKING STATEMENTS TO REFLECT EVENTS OR CIRCUMSTANCES ARISING AFTER THE DATE HEREOF.

#### OVERVIEW

We develop new drug candidates primarily in the antiviral area, with a particular focus on therapies for HIV, including AIDS, and the hepatitis B virus. Our existing portfolio consists of several licensed drug candidates in clinical trials and others that are in a preclinical stage. Members of our senior management team, prior to joining Triangle, played instrumental roles in developing and commercializing several leading antiviral therapies. Our goal is to capitalize on our management team's expertise, as well as on advances in virology and immunology, to identify, develop and commercialize new drug candidates that can be used alone or in combination to treat serious diseases.

Treating HIV infection with combination therapy has shown significant clinical benefits, including reduced virus levels and increased patient longevity. Triangle was founded based in part on our belief that the prolonged use of combination therapy will generate demand for new anti-HIV drugs with favorable activity, resistance, compliance and/or tolerance profiles. We believe the use of anti-HIV drugs will increase because:

- the use of multiple drugs by individual patients on combination therapy will continue to increase,
- previously untreated patients will seek medical care as the benefits of combination therapy become more widely understood, and
- the number of patients and the duration of drug therapy will increase as patient mortality continues to decrease.

We believe that hepatitis B, like HIV, due to its complexity and demonstrated ability to develop resistance, may be more effectively and safely treated with combination therapy.

We are actively developing the following drug candidates which we believe may become valuable tools in the combination treatment of serious viral diseases:

DRUG CANDIDATES TO TREAT HIV

COVIRACIL(R) (EMTRICITABINE), FORMERLY KNOWN AS FTC. A nucleoside analogue, Coviracil has been shown to be a potent inhibitor of HIV and hepatitis B virus replication in laboratory studies. Against HIV, the potency of Coviracil in laboratory studies is 4 to 10 times greater than that of lamivudine, a member of the same nucleoside class as Coviracil. Coviracil is a potent antiviral agent against HIV strains obtained from a geographically diverse set of HIV-infected patients. Laboratory studies have also shown that Coviracil shares cross-resistance patterns with



lamivudine. The most common resistance mutation to these two agents also reverses resistance of the virus to AZT in some cases. We have completed two Phase III clinical studies comparing once-a-day dosage of Coviracil to twice-a-day dosage of lamivudine in combination with other antiviral agents in the treatment of HIV. An additional Phase III clinical study, FTC-301, comparing Coviracil (200 mg once-a-day) to stavudine (40 mg twice-a-day) in combination with didanosine (400 mg once-a-day) and efavirenz (600 mg once-a-day) in antiretroviral therapy naive patients has completed enrollment with 564 patients. We intend to submit a New Drug Application, an NDA, for Coviracil in the third quarter of 2002.

AMDOXOVIR, FORMERLY KNOWN AS DAPD. Amdoxovir, a purine dioxolane nucleoside, may offer advantages over other nucleosides currently in the market because of its activity against drug resistant viruses as exhibited in laboratory studies. This type of activity has also been demonstrated in naive patients and multiple drug failure patients. DAPD-101 was a two-week dose ranging study of amdoxovir either alone or added to the antiviral medications the patient was already receiving. Both drug naive patients and multiple drug failure patients were enrolled in DAPD-101. In treatment naive patients, amdoxovir produced maximum decreases in plasma HIV RNA ranging from 0.54 log(10) to 1.9 log(10) at doses ranging from 25 mg twice-a-day to 500 mg twice-a-day. In 24 patients who had received multiple antiviral therapies, a median viral suppression of 0.66 log(10) was observed when amdoxovir 500 mg twice-a-day was added to the failing antiretroviral regimen.

We are planning to initiate a multi-study Phase II program in 2002 for amdoxovir which is intended to include the following:

- Study DAPD-150, a 96-week randomized trial comparing amdoxovir at 500 mg twice-a-day to 300 mg twice-a-day in combination with best available drug regimen as determined by the patient's physician,

- A 48-week Phase II pilot study of amdoxovir, tenofovir, T20 and Kaletra(R) in highly treatment-experienced patients conducted by the AIDS Clinical Trial Group, ACTG, in the United States,

- A Phase II study, conducted in collaboration with the ACTG, to explore the combination of amdoxovir and mycophenolic acid, which has been shown to significantly enhance the antiviral activity of amdoxovir in the laboratory, and

- A Phase II study, conducted in collaboration with the French Agence Nationale de Recherches sur le Sida, the ANRS, to compare amdoxovir to placebo in patients who have experienced multi-drug failure.

DRUG CANDIDATES TO TREAT HEPATITIS B

EMTRICITABINE, FORMERLY KNOWN AS FTC. We are currently conducting Phase II and Phase III clinical trials with emtricitabine for the treatment of hepatitis B. Some of the development activities we have undertaken with Coviracil for the treatment of HIV will also be used in the assessment of emtricitabine for the treatment of hepatitis B. Emtricitabine has been shown to be a potent inhibitor of hepatitis B virus replication in patients chronically infected with this virus.

Study FTCB-102 is a Phase II randomized, double blind, dose comparison 48-week trial with an additional 48-week open label phase. Enrollment has been completed and 98 patients, 32 or 33 per cohort, have received 25, 100 or 200 mg of emtricitabine once-a-day for 48 weeks. Patients continued to receive 200 mg emtricitabine once-a-day in the open label phase for an additional 48 weeks and have completed their six-month post-treatment follow-up visits. Hepatitis B virus DNA suppression in plasma was measured using the sensitive Digene Hybrid Capture II(R) Assay, with the lower limit of detection of 4,700 copies/mL. Following 48 weeks of treatment, the proportion of patients with undetectable viremia was 38%, 42%, and 61% for the 25 mg, 100 mg, and



200 mg cohorts, respectively. The development of antibodies to and the disappearance of a viral envelope protein, known as Hbe, is evidence of improvement of the condition of a hepatitis B infected patient. This process is called seroconversion and the specific antibody formed is called anti-Hbe. Seroconversion to anti-Hbe occurred in 23% of the patients across all dosage groups. At 48 weeks, Hbe antigen loss occurred in 32%, 38% and 50% of Hbe antigen positive patients in the 25 mg, 100 mg, and 200 mg cohorts, respectively. Accordingly, a 200 mg once-a-day dose was selected for our Phase III studies.

Study FTCB-301 is our first Phase III clinical trial for hepatitis B. It is a randomized, double blind placebo controlled trial comparing 200 mg emtricitabine to placebo in 240 patients. As of March 1, 2002, 182 patients have been randomized in the study. Enrollment is targeted for completion in the second quarter of 2002.

Study FTCB-201 is a 48-week Phase II study comparing a combination of 200 mg emtricitabine and 10 mg adefovir to 10 mg adefovir monotherapy in 30 patients with chronic hepatitis B infections. The study is planned for initiation at one site in Asia in the first quarter of 2002.

CLEVUDINE, FORMERLY KNOWN AS L-FMAU. A pyrimidine nucleoside analogue, clevudine has been shown to be a potent inhibitor of hepatitis B virus replication in laboratory studies, having an EC50 value (the concentration required to inhibit virus by 50%) ranging from 0.02 to 0.15 uM with a mean of 0.08 uM. Clevudine produced an 8 log(10) decrease in the woodchuck model of chronic hepatitis and in three of four animals, woodchuck hepatitis virus DNA remained below

the limit of detection for one year following a three-month treatment period. Chronic toxicology studies have been completed and reproductive toxicology studies are in progress.

We have completed a single-dose, dose escalation Phase I study, L-FMAU-101, with clevudine. Cohorts at 10 mg, 50 mg, and 100 mg once-a-day in Study L-FMAU-102, an ongoing dose escalation Phase I/II one-month monotherapy trial initiated in France, Canada, Hong Kong and South Korea, have completed the 28-day dose period. Median hepatitis B virus DNA decreases at the end of the treatment period were 2.48, 2.74, and 2.95 log(10), respectively. At 20 weeks after the treatment period, the median decrease in hepatitis B virus DNA was 1.92 log(10) at the 10 mg dose and 2.01 log(10) at the 50 mg dose.

Study FTCB-204 is a 48-week Phase II trial being conducted in the United States, Bulgaria, the Czech Republic, Canada and Singapore to evaluate the efficacy of a combination of clevudine and emtricitabine with a 24-week dose period. We expect to enroll approximately 150 patients who were participants in the FTCB-301 study into this trial. We will begin enrolling patients in the second quarter of 2002.

IMMUNOSTIMULATORY SEQUENCES CANDIDATE. In March 2000, we entered into an agreement with Dynavax Technologies Corporation to license immunostimulatory sequencing technology and to test immunostimulatory sequences, ISS, in the treatment of hepatitis B virus. By mixing these shortened strands of DNA with surface antigens, we hope to induce the immune system to develop antibodies against the hepatitis B virus.

- During 2001, Dynavax conducted a double-blind Phase I trial using ISS for hepatitis B virus prophylaxis in 48 patients. The study compared hepatitis B virus surface antigen (HbsAg) alone and co-administered with ISS in doses ranging from 300 to 3,000 micrograms. At the highest dose of ISS tested, the co-administered vaccine produced protective antibody titers in 88% of subjects after one dose. Over all dose levels, 31 of 32 subjects had protective antibody levels after two doses delivered in a two-month regimen.

- During 2002, Triangle plans to test ISS conjugated to hepatitis B surface antigen in animals as a therapeutic vaccine for the treatment of hepatitis B virus. This vaccine is designed to recognize and kill (using a Th1 immune response) hepatitis B virus-infected liver cells that



remain after a patient has been treated with antiviral drugs. We believe that such a response would make ISS a very important component in optimal combination therapy for hepatitis B.

We have not generated any revenue from sales of our drug products and, therefore, are a development stage company. We do not expect to generate any significant revenue from the sale of our drug products before the year 2003. As of December 31, 2001, our accumulated deficit was $406.9 million. We may never achieve profitable operations or generate positive cash flow.

Triangle was incorporated in Delaware in July 1995. Our principal executive offices are located at 4 University Place, 4611 University Drive, Durham, North Carolina 27707, and our telephone number is (919) 493-5980.

STRATEGY

Our goal is to create a portfolio of commercialized drugs primarily for serious viral diseases. We intend to achieve this goal through the following strategies:

FOCUS ON VIRAL DISEASES. The expertise of our management team lies in identifying, developing and commercializing drugs for the treatment of viral diseases. We are targeting the viral disease markets because we believe the significant unmet medical need and the rapid pace of scientific advances occurring in the treatment of these diseases give these significant markets attractive growth potential. We also believe that the relatively high concentration of prescribers that treat patients with HIV and hepatitis B infections will enable us to promote most drug candidates through a small, specialized sales force.

FOCUS ON DRUG DEVELOPMENT, NOT DRUG DISCOVERY. We do not currently intend to engage in a significant level of basic drug discovery, thereby we expect to avoid much of the significant investment of time and capital that is generally required before a compound is identified and brought to clinical trials. We intend to use our expertise to perform internally what we believe are the most critical aspects of the drug development process, such as the design of clinical trials and the optimization of drug synthesis. We outsource many aspects of our clinical trials and the manufacture of drug substance to carefully selected third parties.

APPLY SELECTIVE CRITERIA TO DRUG CANDIDATES. When we evaluate drug candidates for our product development programs, we seek to in-license drug candidates for which favorable preclinical, and where possible, clinical data already exist. We intend to use our expertise to identify drug candidates that we judge to have attractive preclinical profiles. In addition, we prefer, where practical, to in-license drug candidates that have either undergone some testing in humans, such as Coviracil, or share characteristics with drugs that are currently approved for use in humans. We intend to apply these selection standards where feasible in evaluating potential drug candidates for in-licensing.

LEVERAGE RELATIONSHIPS. As a result of our instrumental roles in the identification, clinical development and commercialization of antiviral therapies, our management team and scientific consultants have extensive contacts in academia and industry. These contacts were instrumental in the acquisition of our existing drug candidates, and we believe they will be valuable in our efforts to develop and to commercialize existing and future drug candidates.

DEVELOP DRUGS FOR USE IN COMBINATION THERAPY. Combination therapy is the accepted method to treat viral diseases such as HIV infection. We seek to identify and develop drug candidates for use in combination therapy that have resistance, compliance and/or tolerance profiles that are complementary to the profiles of existing drugs. In addition, in contrast to the competitive marketing of single drug regimens, we believe that any drug we develop as part of a combination regimen will benefit from the promotional efforts of the marketers of the other drugs in the regimen.

FOCUS ON SMALL MOLECULE DRUGS. Our management team is well known for its successful development of and expertise in small molecule drugs, and nucleosides in particular. Small molecule drugs have several advantages over large molecule drugs such as proteins, polypeptides and polynucleotides. For example, small

molecule drugs are often simpler to scale-up and manufacture than large molecule drugs, and are more likely to be orally



bioavailable (taken by mouth) which is a significant advantage in treating long-term chronic illnesses where patients prefer not to be subjected to injections over extended periods of time.

STRATEGICALLY OUTSOURCE ROUTINE ASPECTS OF DRUG DEVELOPMENT. Our strategy is to remain focused on drug development. Much of the drug development process consists of routine elements that may be outsourced to high quality, high capacity contractors. Accordingly, we intend to focus our corporate resources on the aspects of drug development that require particular expertise. For example, we intend to concentrate on the design of clinical trials and the optimization of drug synthesis, and to outsource many aspects of the conduct of clinical trials and the manufacture of drug substance. We believe this strategy enables us to respond rapidly to certain changing events, such as clinical trial results and the availability of funds, by increasing or decreasing expenditures on particular drug development projects or by shifting our emphasis among projects.

LEVERAGE STRATEGIC ALLIANCE ADVANTAGES. Since our inception, our strategy has been to develop third party relationships to enhance our drug development process and to commercialize our drug candidates thereby reducing the amount of internal infrastructure to develop and successfully commercialize our drug candidates. Our worldwide strategic alliance with Abbott Laboratories, the Abbott Alliance, provides us with access to Abbott's international and domestic infrastructure to market and distribute products receiving regulatory approval, global manufacturing capability, drug development assistance, United States co-promotion rights to Kaletra, one of Abbott's compounds, as well as financial support to help fund the continued development of our portfolio of drug candidates. We believe that the high concentration of major prescribers of anti-HIV and anti-hepatitis B therapies in the United States will enable us to promote most drug candidates that we may successfully develop to these prescribers through a small sales force or through arrangements or collaborations with third parties. In the United States, we intend to market our drug candidates covered by the Abbott Alliance in collaboration with Abbott and to market other drug candidates we may successfully develop, that do not become part of the Abbott Alliance, through a small sales force or through arrangements or collaborations with third parties. Outside of the United States, we expect Abbott to market drug candidates covered by the Abbott Alliance and, for any other drug candidates we successfully develop that do not become part of the Abbott Alliance, we intend to market and sell through arrangements or collaborations with third parties. As part of the ordinary course of our business, we may consider arrangements or collaborations with third parties associated with the acquisition, development, marketing and sales of our products both within and outside of the United States.



DRUG CANDIDATES IN CLINICAL DEVELOPMENT

| DRUG CANDIDATES | INDICATION | STATUS(1),(2) | TERRITORY(3) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Coviracil(R) (emtricitabine), FORMERLY KNOWN AS FTC | HIV | Phase III | Worldwide |
| | hepatitis B | Phase III | Worldwide |
| Amdoxovir, FORMERLY KNOWN AS DAPD | HIV | Phase II | Worldwide |
| Clevudine, FORMERLY KNOWN AS L-FMAU | hepatitis B | Phase II | Worldwide, except Korea |
| Immunostimulatory sequences candidate | hepatitis B | Phase I | Worldwide |

(1) Neither the Food and Drug Administration, FDA, nor any foreign regulatory agencies have approved our drug candidates for commercial sale.

(2) "Phase I" means that we are testing a drug candidate for preliminary indications of safety, pharmacokinetics and tolerance in a limited number of patients or volunteers. "Phase II" means that we are testing a drug candidate for safety, efficacy and, in some cases, optimal dosage in a limited number of patients. "Phase III" means that we are conducting expanded clinical studies intended to support a submission for regulatory approval of a drug candidate.

(3) Indicates the geographic territory in which we have licensed the right to commercialize the particular product. Coviracil, amdoxovir and clevudine are drug candidates under the Abbott Alliance. Our ability to commercialize products in each country in the licensed territory may be limited by proprietary rights of third parties other than our licensors.



VIRAL DISEASE PROGRAM

HIV

BACKGROUND. The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that as of the end of 2001, 40 million people worldwide were living with HIV or AIDS. It is generally believed that, in the absence of therapeutic intervention, the vast majority of individuals infected with HIV will ultimately develop AIDS, which if untreated has a mortality rate approaching 100%. There are an estimated 900,000 persons living with HIV/AIDS in North America, with nearly 40,000 new infections annually in the United States, and approximately one third are receiving antiviral therapy. Sales of antiretroviral therapies in the United States for the 12 months ended December 2001 totaled over $4 billion, which represents a 19% increase as compared to 2000.

Experts believe a key factor in how quickly a person infected with HIV develops AIDS is the amount of HIV in the body at any one time, known as the viral load. The failure of vaccines and other immunotherapy to control the virus has led current researchers to focus on halting HIV replication and reducing viral load by blocking one or both of two key enzymes required for viral replication.

The first enzyme, reverse transcriptase, is active early in the replication cycle and allows the virus, which is made of RNA, to transform to its DNA form necessary for continued replication. This enzyme can be inhibited by two general classes of drugs defined both by their structure as well as their mechanism of action. The first general class, nucleoside analogue reverse transcriptase inhibitors, NRTIs, such as AZT, ddI, d4T and lamivudine, bears a

strong chemical resemblance to the natural building blocks (nucleotides) of DNA and interferes with the function of the enzyme by displacing the natural nucleotides used by the enzyme. The second general class, non-nucleoside reverse transcriptase inhibitors, NNRTIs, such as nevirapine, delavirdine and efavirenz, is composed of an extremely diverse group of chemicals that act by attaching to the reverse transcriptase enzyme and modifying it so that it functions less efficiently. The second enzyme, protease, is required to permit full virus maturation. Inhibitors of this enzyme are represented by drugs such as saquinavir, ritonavir, indinavir and nelfinavir.

The genetic material responsible for the production of both enzymes is extremely prone to mutations that can produce resistance to drugs targeted at these enzymes. If antiviral therapy does not halt all viral replication, then mutant strains of virus continue to replicate. Depending upon the particular mutations that occur, these virus strains may be resistant to only one of the drugs used in therapy or may be resistant to some or all of the drugs in the same chemical or functional class. This latter phenomenon is known as cross-resistance.

Initially, HIV was treated only with AZT, a NRTI, which was first introduced in 1987. Three other NRTIs--ddI, ddC and d4T --were introduced to the market in the early 1990's. These drugs, when used alone, provided only short-term clinical benefit, could be toxic and were often considered expensive relative to their clinical benefits. As a result, the use of anti-HIV therapy was limited (less than 25% of the infected population in the United States).

More recently, clinical research in HIV has been facilitated by the introduction in the mid-1990's of tests that can reliably determine the viral load in the blood at any given time. As a result, it became possible to rapidly evaluate potential therapeutic agents and combinations of agents and to determine accurately the potency and resistance profiles of these agents. This has led to the accelerated development of a number of new therapeutic agents and their use in combination therapy. The use of combination therapy, including combinations of protease inhibitors or NNRTIs with two NRTIs, has demonstrated significant therapeutic benefit, sometimes rendering the virus undetectable in the blood of certain patients for over several years. Additional combinations may be possible as new therapeutic agents are developed.

In spite of these significant advances, numerous challenges remain in the treatment of HIV. In the absence of a cure, the disease is life long. Although combination therapy has demonstrated the ability to markedly slow resistance development, mutants have been identified which are resistant to the drugs currently used during the course of combination therapy studies, and cross-resistance among many agents, including protease inhibitors, has been increasingly recognized. Present combination treatments are also often complex and expensive. Adverse



reactions to many of the drugs used in combination therapy are common and may limit adherence to the therapeutic regimen or even preclude use in some patients. Even brief instances of non-adherence can reduce or eliminate the ability of the combination therapy to suppress the virus, and may thus accelerate the development of resistance. We believe that these challenges present an opportunity to develop additional drugs that have attractive safety, pharmacokinetic and/or resistance profiles.

DEVELOPMENT STATUS. We have two drug candidates for the treatment of HIV: Coviracil and amdoxovir.

COVIRACIL (EMTRICITABINE), FORMERLY KNOWN AS FTC. We are currently conducting Phase III clinical trials with Coviracil for the treatment of HIV. We have licensed worldwide rights to Coviracil for the treatment of HIV and hepatitis B from Emory University.

Coviracil is a fluorinated nucleoside analog and is a member of the same nucleoside series as lamivudine, the most commonly prescribed drug for HIV disease. Against HIV, the potency of Coviracil in laboratory studies is 4 to 10 times greater than that of lamivudine, and is a potent antiviral agent against HIV strains obtained from a geographically diverse set of HIV-infected patients. Laboratory studies have also shown that Coviracil shares cross-resistance patterns with lamivudine. In some cases, the most common resistance mutation to these two agents also reverses resistance of HIV to AZT.

A Phase I single dose study evaluated the pharmacokinetics and tolerance of Coviracil in 12 HIV-infected volunteers. The volunteers received six single oral doses of Coviracil at six-day intervals ranging from 100 mg to 1,200 mg. Coviracil was well tolerated by all subjects in the dose range studied. Coviracil was absorbed rapidly into the blood stream following oral administration and was excreted primarily through the kidneys. While food intake slightly delayed absorption, it did not affect the overall oral bioavailability. The absorption, metabolism and excretion of Coviracil were generally consistent among the subjects.

In a Phase I/II monotherapy study in 41 HIV-infected patients, doses of Coviracil ranging from 25 mg twice-a-day to 200 mg twice-a-day were given for two weeks. A brief duration of monotherapy exposure was selected to limit the development of viral resistance, but allowed a preliminary assessment of drug candidate tolerance and antiviral activity. At each dose regimen containing doses of 200 mg/day or more, a 98% (1.75 log(10)) or greater viral suppression was observed. A single, once-a-day, 200 mg dose reduced the viral load by an average of 99% (1.92 log(10)). The drug was generally well tolerated, with the most frequently observed adverse experiences being headache, nausea/vomiting, and diarrhea.

In an additional monotherapy study used to determine the optimum dose of Coviracil, 80 patients were randomized to receive one of three doses of Coviracil, 25, 100 or 200 mg, once-a-day or the standard dose of lamivudine, 150 mg twice-a-day. Patients were treated for ten days and followed for an additional two days after the completion of dosing. All regimens were active, but the dose of 200 mg of Coviracil exhibited superior antiviral suppression. This effect was determined by a number of variables including calculations of absolute changes in viral load, average area under the curve minus baseline, and the slope of viral RNA decay. Of those receiving 200 mg of Coviracil, at the end of therapy 58% (11/19) had either a 2 log(10) drop in viral load or a reduction in virus below the level of detection and, of these, 21% (4/19) had both. Even two days after the completion of this short course of therapy, the absolute decrease in viral load was 1.63 log(10) (43-fold decrease).

In a Phase II study, known as the Montana Study, sponsored by the ANRS in France, 40 antiretroviral naive HIV-infected patients received a once-a-day regimen of Coviracil (200 mg), ddI and efavirenz. The median plasma HIV RNA level at baseline was approximately 60,000 copies/mL. The once-a-day combination was generally well tolerated and demonstrated strong antiviral and favorable immunologic effects that were sustained during the 96-week observation period. After 96 weeks of therapy, 85% of patients (34/40) maintained plasma HIV RNA levels below 400 copies/mL and 80% of patients (32/40) maintained plasma HIV-1 RNA levels below 50 copies/mL on an intent-to-treat basis. The median baseline CD4 count was 373 cells/mL, increasing by a median of 259 cells/mL at week 96. The most common treatment-related adverse events were reported during the first 24 weeks of the study. Two patients developed elevated triglycerides that may have been treatment related; only three patients stopped trial treatment because

of adverse events.



Based on the favorable results of the Montana Study, we have conducted a Phase III study in collaboration with the ANRS comparing two treatment strategies for patients with HIV-1 infection. In this study, the ALIZE study, patients were randomized to stay on their pre-existing triple combination regimen or replace it with the once-a-day regimen of Coviracil (200 mg), ddI, and efavirenz. Three hundred fifty-five patients were enrolled in the ALIZE study with the last patient reaching the week 48 visit in March 2002.

We have also completed two randomized, controlled Phase III studies, FTC-302 and FTC-303, and have completed enrollment for a third randomized, controlled Phase III clinical study, FTC-301. FTC-302 and FTC-303 compared Coviracil (200 mg once-a-day) to lamivudine (150 mg twice-a-day) in triple therapy combination regimens. FTC-303 was an open-label switch study of 440 HIV-infected patients in the United States whose viremia had been fully-suppressed (<400 copies/mL) with a lamivudine-containing regimen. Patients were required to have been on lamivudine for at least 12 weeks at study entry and were randomly selected to switch in a two to one ratio from twice-a-day lamivudine to once-a-day Coviracil or remain on twice-a-day lamivudine. FTC-302 was a randomized, double-blind study that compared Coviracil to lamivudine in a background of stavudine (d4T) and either nevirapine (in patients with baseline HIV-1 RNA levels less than or equal to 100,000 copies/mL) or efavirenz (in patients with baseline HIV-1 RNA levels greater than 100,000 copies/mL) in 468 antiretroviral treatment naive HIV-infected patients. In April 2000, the South African Medicines Control Council terminated FTC-302 and the FDA issued a clinical hold on the study. Subsequently, the FDA advised us that FTC-302 will not be considered a pivotal study in support of an NDA. FTC-301 is a randomized, double-blind study that has completed enrollment of 564 antiretroviral naive patients. FTC-301 is designed to compare Coviracil (200 mg once-a-day) to stavudine (40 mg twice-a-day) in combination with didanosine (400 mg once-a-day) and efavirenz (600 mg once-a-day). We expect this study to complete its 48 weeks end point in October 2002. Upon obtaining and analyzing 24-week data, we plan to submit an NDA for Coviracil for the treatment of HIV in the third quarter of 2002. The FDA will require that 48 weeks of data from FTC-301 be incorporated into our NDA submission during the review process.

Antiviral effect was measured in FTC-302 and FTC-303 by a number of different analyses. Data from FTC-302 indicate that 60% and 64% of patients in the Coviracil and lamivudine groups, respectively, had fewer than 50 copies/mL of HIV RNA in their plasma at week 48 on an intent-to-treat, missing equals failure basis. The incidence of virologic failure associated with resistance development was the same in both groups (approximately 9.6%). In FTC-303, loss of virologic suppression at any time during the 48-week observation period occurred in only 8% of patients in each treatment arm.

Both Coviracil and lamivudine were generally well tolerated by the majority of patients in both studies. Adverse reactions were predominantly mild to moderate in both groups with the exception of some episodes of severe liver toxicity in FTC-302. In this study, severe liver toxicity was seen in 17% of the patients receiving nevirapine (15% in the Coviracil arm and 19% in the lamivudine arm), whereas none of the patients receiving efavirenz concomitantly with Coviracil or lamivudine developed such hepatotoxicity. The overall rate of liver toxicity observed in FTC-302 is consistent with the frequency observed in other published studies with nevirapine, including those where neither Coviracil nor lamivudine was part of the regimen.

Estimated subsequent costs necessary to get through the FDA approval

process and launch Coviracil as a commercial product to treat HIV are projected to be $33 million to $38 million, excluding the cost of pre-launch inventory. These costs include completing FTC-301 and the ALIZE study, additional chemical development work, production of additional clinical trial material, salaries for development personnel, other unallocated development costs and regulatory preparation and filing costs. These costs are difficult to estimate and actual costs could be higher than our estimates, for example, if the clinical trials for Coviracil do not proceed as planned, if our NDA is delayed or on the occurrence of other events described under the caption "Risk and Uncertainties."

AMDOXOVIR, FORMERLY KNOWN AS DAPD. We have initiated Phase I/II clinical trials with amdoxovir for the treatment of HIV. We have licensed worldwide rights to amdoxovir for the treatment of HIV and hepatitis B from Emory and the University of Georgia Research Foundation, Inc., University of Georgia.

Amdoxovir may offer advantages over other nucleosides currently in the market and may offer benefit to patients because of its unique structure which leads to activity in the laboratory against certain resistant strains of HIV. Amdoxovir is synergistic with a number of antivirals, such as Coviracil and AZT, in laboratory studies. HIV



strains that are resistant to AZT, lamivudine or Coviracil are not cross-resistant to amdoxovir. Studies in animals and humans have demonstrated the majority of amdoxovir is rapidly converted to dioxolane guanosine, DXG, the active anti-HIV agent. Preliminary analyses of these pharmacokinetic studies indicate that DXG serum concentrations decline with a half-life of seven to nine hours. The analysis of urine samples from this study indicate the presence of DXG with no other metabolites detected. We presented initial results from a Phase I/II 14-day monotherapy study. Thirty-four antiviral drug-naive patients received monotherapy doses of 25, 100, 200, 300 and 500 mg of amdoxovir twice-a-day. The maximum median viral load decreases were 0.54 log(10), 1.0 log(10), 1.14 log(10), 1.49 log(10) and 1.9 log(10), respectively. At all doses tested, viral suppression was observed and suggested a dose effect relationship. The drug was well tolerated at all doses tested with no significant or consistent adverse effects during the dosing period. In addition, 26 patients with extensive prior antiretroviral therapy (5.8 - 6.5 prior drugs for 3.7 - 4.6 years) received monotherapy doses of 200, 300 and 500 mg twice-a-day. The maximum median viral load decreases were 0.5 log(10), 0.5 log(10), and 1.1 log(10), respectively. Twenty-four patients who had experienced multiple drug failure experienced a median viral load decrease of 0.66 log(10) when amdoxovir was added to the failing regimen at 500 mg twice-a-day.

We are planning to initiate a multi-study Phase II program in 2002 for amdoxovir which is intended to include the following:

- Study DAPD-150, a 96-week randomized trial comparing amdoxovir at 500 mg twice-a-day to 300 mg twice-a-day in combination with best available drug regimen as determined by the patient's physician,
- A 48-week Phase II pilot study of amdoxovir, tenofovir, T20 and Kaletra(R) in highly treatment-experienced patients conducted by the ACTG in the United States,
- A Phase II study, conducted in collaboration with the ACTG, to explore the combination of amdoxovir and mycophenolic acid, which has been shown to significantly enhance the antiviral activity of amdoxovir in the laboratory, and

- A Phase II study, conducted in collaboration with the ANRS to compare amdoxovir to placebo in patients who have experienced multi-drug failure.

In order to submit an NDA for amdoxovir, we will need to complete the ongoing trials, the Phase II program as described above and a Phase III program to be developed based on the clinical profile of the compound indicated by the Phase II data. Estimated subsequent costs necessary to get through the regulatory approval process and launch the drug candidate are projected to be $67 million to $97 million. These costs, excluding the cost of pre-launch inventory, would include a Phase III clinical program, manufacturing amdoxovir and providing medications for combination therapy to clinical trial participants, additional chemical development work, production of qualification lots consistent with current Good Manufacturing Practice standards, salaries for development personnel, other unallocated development costs and regulatory preparation and filing costs. These costs are difficult to estimate and actual costs could be higher than our estimates, for example, if the clinical trials for amdoxovir do not proceed as planned, if our ability to file an NDA is delayed or on the occurrence of other events described under the caption "Risk and Uncertainties."

The FDA has notified us that amdoxovir qualifies for "fast track" designation under provisions of the Food and Drug Administration Modernization Act of 1997. A fast track designation may expedite the FDA's review of our NDA for amdoxovir.

HEPATITIS B

BACKGROUND. Hepatitis B virus is the causative agent of both the acute and chronic forms of hepatitis B, a liver disease that is a major cause of illness and the ninth leading cause of death throughout the world. It is estimated that over two billion individuals worldwide have been infected with hepatitis B virus, of which approximately 300-350 million are considered chronic carriers of the disease. Many chronic carriers of the virus show no signs of disease; however 25-30% experience symptomatic disease, which may lead to the development of cirrhosis or liver cancer. Hepatitis B virus infection is prevalent in Southern Europe, Africa, South America, and



particularly, Asia. Over two-thirds of the world's chronic carriers are thought to reside in Asia, with China representing over half of these infections. In the United States, it is estimated that over one million individuals are chronic carriers of hepatitis B virus, and despite the availability and aggressive use of vaccines against the virus, the number of infected individuals continues to grow, with 1.7 million chronic carriers in the United States projected by the year 2010.

Vaccines are currently available that can prevent the transmission of hepatitis B virus; however, these vaccines have no efficacy in those already infected. Alpha interferon (a commercially available drug approved for the treatment of hepatitis B) is administered by injection, is not always successful in controlling the virus and is associated with significant side effects, the most common being severe "flu-like" symptoms. While other compounds have activity in the treatment of hepatitis B virus infection, we believe additional drugs will be necessary to effectively treat the disease. For example, lamivudine (a commercially available drug approved for the treatment of hepatitis B) has shown good tolerance and effective suppression of hepatitis B virus replication during the course of treatment. However, virus replication can return during prolonged therapy. Studies of more prolonged therapy are in

progress, and antiviral resistance has been observed with certain patients.

We believe that hepatitis B, like HIV, may be treated more effectively with combination therapy. Therefore, even if other drugs are approved for the treatment of hepatitis B, we believe there will still be a need for additional safe and effective oral therapies for chronic hepatitis B that can be used in combination therapies.

EMTRICITABINE, FORMERLY KNOWN AS FTC. We are currently conducting Phase II and Phase III clinical trials with emtricitabine for the treatment of hepatitis B. Some of the development activities we have undertaken with Coviracil for the treatment of HIV will also be used in the development of emtricitabine for the treatment of hepatitis B.

Emtricitabine has been shown to be a potent inhibitor of hepatitis B replication in laboratory studies, and is synergistic in laboratory studies in combination with several other compounds intended for the treatment of hepatitis B. The anti-hepatitis activity of emtricitabine has been demonstrated in a chimeric mouse model and against woodchuck hepatitis virus, WHV, in naturally infected woodchucks. The hepatitis infection of the woodchuck results in a disease state closely resembling that found in humans infected with hepatitis B. In the woodchuck model at doses above 3 mg/kg, all treated animals had significantly reduced levels of WHV DNA in their blood. One week after treatment was stopped, WHV levels returned to pretreatment levels, as is seen with lamivudine.

A Phase I/II dose-response trial of emtricitabine has been completed in patients with chronic hepatitis B infection from the United States and Hong Kong. Patients received non-randomized, escalating doses of emtricitabine of 25 mg to 300 mg once-a-day for eight weeks. Emtricitabine was generally well tolerated throughout the trial. At 56 days of treatment, the median change from baseline in plasma hepatitis B virus DNA ranged from -1.7 to -3.3 log(10).

Study FTCB-102 is a Phase II randomized, double blind, dose comparison 48-week trial with an additional 48-week open label phase. Enrollment has been completed and 98 patients, 32 or 33 per cohort, have received 25, 100 or 200 mg emtricitabine once-a-day for 48 weeks. Patients continued to receive 200 mg emtricitabine once-a-day in the open label phase for an additional 48 weeks and have completed their six-month post therapy follow-up visits. Hepatitis B virus DNA suppression in plasma was measured by the Digene Hybrid Capture II Assay. Following 48 weeks of treatment, the proportion of patients with undetectable viremia was 38%, 42%, and 61% for the 25 mg, 100 mg, and 200 mg cohorts, respectively. Seroconversion to anti-Hbe occurred in 23% of the patients across all dosage groups. At 48 weeks, Hbe antigen loss occurred in 32%, 38% and 50% of Hbe antigen positive patients in the 25 mg, 100 mg, and 200 mg cohorts, respectively. Accordingly, a 200 mg once-a-day dose was selected for our Phase III development.

Study FTCB-301 is a Phase III clinical trial. It is a 48-week randomized, double blind, placebo controlled trial comparing 200 mg emtricitabine to placebo in 240 patients. As of March 1, 2002, 182 patients have been randomized in the study. Enrollment is targeted for completion in the second quarter of 2002.



Study FTCB-201 is a 48-week Phase II study comparing a combination of 200 mg emtricitabine and 10 mg adefovir to 10 mg adefovir monotherapy in 30 patients with chronic hepatitis B infections. The study is planned for initiation at one site in Asia in the first quarter of 2002.

Excluding the cost of pre-launch inventory, estimated subsequent costs necessary to obtain regulatory approval and launch emtricitabine as a commercial product to treat hepatitis B are projected to be $38 million to $44 million. These costs include completing all ongoing studies (including FTCB-301), at least one additional Phase III clinical trial, additional chemical development work, production of qualification lots consistent with current Good Manufacturing Practice standards, salaries for development personnel, other unallocated development costs and regulatory preparation and filing costs. These costs are difficult to estimate and actual costs could be higher than our estimates, for example, if the clinical trials for emtricitabine for the treatment of hepatitis B do not proceed as planned, if regulatory filings are delayed or on the occurrence of other events described under the caption "Risk and Uncertainties."

CLEVUDINE, FORMERLY KNOWN AS L-FMAU. Clevudine is a pyrimidine nucleoside analogue that has been shown to be a potent inhibitor of hepatitis B replication in laboratory studies. The effective concentration of clevudine required to inhibit virus growth by 50% (EC(50)) ranges from 0.02 to 0.15 uM with a mean of 0.08 uM. Laboratory studies have also shown that clevudine has activity against the Epstein Barr virus. We have licensed worldwide rights to clevudine, except in Korea, from Bukwang Pharm. Ind. Co., Ltd., for all human antiviral applications and are developing it as a treatment for chronic hepatitis B infections.

In laboratory studies, the efficacy of clevudine has been demonstrated in woodchucks chronically infected with WHV. Within seven days of initial treatment, large reductions in serum WHV DNA were observed over a range of doses. A once-a-day dose of 10 mg/kg clevudine decreased WHV DNA by 8 logs; the virus did not return for one year after cessation of dosing in the majority of animals dosed for four and 12 weeks, respectively. Chronic toxicology studies have been completed and reproductive toxicology studies are in progress.

We have completed a single-dose, dose escalation Phase I study, L-FMAU-101, with clevudine in which kinetics were linear over the 150 to 1,200 mg dose range. Study L-FMAU-102 is a dose escalation 28-day monotherapy Phase I/II trial in progress in France, Canada, Hong Kong and South Korea. Cohorts at 10 mg, 50 mg, and 100 mg once-a-day have completed the 28-day dose period. Median hepatitis B virus DNA decreases at the end of the treatment period were 2.48, 2.74, and 2.95 log(10), respectively. At 20 weeks after the treatment period, the median decrease in hepatitis B virus DNA remained at 1.92 log(10) at the 10 mg dose and 2.01 log(10) at the 50 mg dose.

Study FTCB-204 is a Phase II trial to evaluate the efficacy of a combination of 10 mg clevudine and 200 mg emtricitabine in approximately 150 patients who complete the FTCB-301 trial. The study is being conducted in the United States, Bulgaria, the Czech Republic, Canada and Singapore and patients will begin enrolling in the second quarter of 2002.

We will need to analyze data from ongoing studies to develop additional clinical trials for this compound. We expect that we will be required to complete one or two additional Phase II trials and a Phase III program. Estimated subsequent costs necessary to obtain regulatory approval and launch clevudine as a commercial product to treat hepatitis B virus are projected to be $67 million to $92 million. These costs, excluding the cost of pre-launch inventory, include completing all ongoing and additionally required clinical trials, manufacturing clevudine and providing medications for combination therapy to clinical trial participants, additional chemical development work, production of qualification lots consistent with current Good Manufacturing Practice standards, salaries for development personnel, other unallocated development costs and regulatory preparation and filing costs. These costs are difficult to estimate and actual costs could be higher than our estimates, for example, if the clinical trials for clevudine do not proceed as planned, if

regulatory filings are delayed or on the occurrence of other events described under the caption "Risk and Uncertainties."

IMMUNOSTIMULATORY SEQUENCES CANDIDATE.

ISS are short sequences of synthetic single-strand DNA which induce the immune system to fight pathogens and counterbalance allergic responses. Dynavax is currently using ISS in three ways to exploit their numerous potential therapeutic applications: linked to allergens for the treatment of allergies and asthma, linked to



antigens to enhance prophylactic and therapeutic vaccines and cancer immunotherapy, and administered in an unlinked form as a drug for therapeutic intervention in infection and inflammatory diseases.

In March 2000, we entered into an agreement with Dynavax to license immunostimulatory sequencing technology and to test ISS in the treatment of HIV, hepatitis B virus and hepatitis C virus. By mixing these shortened strands of DNA with surface antigens, we hope to induce the immune system to develop antibodies against the hepatitis B virus.

- During 2001, Dynavax conducted a double-blind Phase I trial using ISS for hepatitis B virus prophylaxis in 48 patients. The study compared hepatitis B virus surface antigen (HbsAg) alone and co-administered with ISS in doses ranging from 300 to 3,000 micrograms. At the highest dose of ISS tested, the co-administered vaccine produced protective antibody titers in 88% of subjects after one dose. Over all dose levels, 31 of 32 subjects had protective antibody levels after two doses delivered in a two-month regimen.

- During 2002, Triangle plans to test ISS conjugated to hepatitis B surface antigen in animals as a therapeutic vaccine for the treatment of hepatitis B virus. This vaccine is designed to recognize and kill (using a Th1 immune response) hepatitis B virus-infected liver cells that remain after a patient has been treated with antiviral drugs. We believe that such a response would make ISS a very important component in optimal combination therapy for hepatitis B.

Based on preclinical data, we believe we may be in a position to file an Investigational New Drug Application, IND, and begin Phase I clinical trials in 2003. Given the limited data available for this drug candidate, we are unable to project the scope and cost of future clinical development of ISS.

LICENSE AND OTHER MATERIAL AGREEMENTS

ABBOTT LABORATORIES. In August 1999, we completed a worldwide strategic alliance with Abbott which now covers four antiviral compounds. Under the terms of the Abbott Alliance, Triangle and Abbott will collaborate with respect to the clinical development, registration, distribution and marketing of various proprietary pharmaceutical products for the prevention and treatment of HIV and hepatitis B virus. In the United States, Triangle and Abbott will co-promote three Triangle drug candidates currently in active development for HIV and/or hepatitis B, Coviracil, amdoxovir and clevudine, and Abbott's HIV protease inhibitor Kaletra. Outside the United States, Abbott has exclusive sales and marketing rights to promote the three Triangle antiviral compounds and Kaletra. Triangle and Abbott will share profits and losses for the three Triangle drug candidates. Triangle will receive detailing fees and commissions on incremental

sales we generate for Kaletra. In addition, Abbott will have the right of first discussion to market future Triangle compounds until 2005. The Abbott Alliance provides for non-contingent research funding of $31.7 million, $25.0 million of which was received in 1999 and $6.7 million of which was received in 2000, and up to $120 million of contingent development milestone payments and the sharing of future commercialization costs. In addition, Abbott initially purchased approximately 6.57 million shares of Triangle common stock at $18.00 per share with net proceeds to us of approximately $115.9 million. Under the terms of the Abbott Alliance, Abbott has the right to purchase additional amounts of our common stock up to a maximum aggregate percentage of 21% of our outstanding common stock and in several situations has rights to purchase shares directly from us in order to maintain its existing level of ownership. Abbott has subsequently purchased an additional 1.37 million shares with net proceeds to us of approximately $8.2 million. The Abbott Alliance provides us with access to Abbott's international and domestic infrastructure to market and distribute products receiving regulatory approval, global manufacturing capabilities, drug development assistance, United States co-promotion rights to Kaletra, as well as financial support to help fund the continued development of our portfolio of drug candidates.

We have licensed Coviracil from Emory; amdoxovir from Emory and the University of Georgia; clevudine from Bukwang; and the immunostimulatory sequences candidate from Dynavax.



EMORY UNIVERSITY AND UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC.

COVIRACIL. In April 1996, we entered into a license agreement with Emory pursuant to which we received an exclusive worldwide license to all of Emory's rights to purified forms of emtricitabine for use in the HIV and the hepatitis B fields. As consideration for the exclusive license of the emtricitabine technology, we issued 500,000 shares of common stock to Emory and agreed to pay certain license fees, all of which have been paid to Emory. In addition, we agreed to make certain milestone and royalty payments to Emory. Beginning the third year after the first FDA registration is granted for an anti-HIV product incorporating the emtricitabine technology in the United States and the third year after the first registration is granted for an anti-hepatitis B product incorporating the emtricitabine technology in certain major market countries, we will be required to pay Emory minimum annual royalties for the HIV and hepatitis B indications, respectively. Under the license agreement, Emory is primarily responsible for prosecuting all patents related to the emtricitabine technology. We agreed to reimburse Emory for the patent prosecution costs it incurs after December 1996. We have the right to pursue any actions against third parties for infringement of the emtricitabine technology at our expense. Upon the conclusion of any such infringement action we pursue, we are entitled to offset unrecovered expenses incurred in connection with the infringement action against a percentage of the aggregate milestone payments and royalties owed to Emory during the time the infringement action was pending. In addition, we are obligated to defend, indemnify and hold harmless Emory and certain of its representatives against any claims or losses incurred as a result of our manufacturing, testing, design, use and sale of products utilizing the emtricitabine technology. Emory has the right to terminate the license agreement or to convert the exclusive license to a nonexclusive license in the event we do not satisfy certain milestone obligations. Emory may also terminate the license agreement upon an uncured breach of the agreement by us. In the event of a termination or conversion for our breach or failure to meet milestone obligations, we will grant Emory certain nonexclusive, royalty-free license rights in all intellectual property under our control relating to the emtricitabine technology necessary for the marketing of products incorporating

the emtricitabine technology. The termination of the license agreement or the conversion from an exclusive to a nonexclusive agreement would adversely affect our business.

In May 1999, Emory and GlaxoSmithKline plc, Glaxo, settled their litigation pending in the United States District Court relating to Coviracil, and we became the exclusive licensee of the United States and all foreign patent applications and patents filed by Burroughs Wellcome Co. on the use of emtricitabine to treat hepatitis B. Pursuant to the license and settlement agreements, Emory and Triangle were also given access to development and clinical data and drug substance held by Glaxo relating to emtricitabine.

In February 2002, Shire Pharmaceuticals Group, plc issued a press release announcing that Shire Pharmaceuticals and Glaxo have agreed to the material terms of a settlement agreement with Emory resolving the worldwide patent disputes between the parties relating to lamivudine and the disputes between Shire Pharmaceuticals and Emory relating to Coviracil. The settlement would provide a license to Emory under Shire Pharmaceuticals' patent rights covering the manufacture, use and sale of Coviracil. Under the terms of our license with Emory, Shire Pharmaceuticals' patent rights on Coviracil flow from Emory to us by sublicense. The settlement has not been finalized and the definitive settlement may differ from the material terms disclosed.

AMDOXOVIR. In March 1996, we entered into a license agreement with Emory and University of Georgia pursuant to which we received an exclusive worldwide license to all of Emory's and University of Georgia's rights to a series of nucleoside analogues including amdoxovir and DXG (i.e., the active anti-HIV agent) for use in the HIV and hepatitis B fields. As consideration for the exclusive license of the amdoxovir technology, we issued an aggregate of 150,000 shares of common stock to Emory and University of Georgia. In addition, we agreed to make certain milestone and royalty payments to Emory and University of Georgia. In March 1999, we began paying license maintenance fees because certain development milestones had not yet been achieved. Beginning the third year after the first FDA registration is granted for an FDA-approved product incorporating the amdoxovir technology, we will be required to pay Emory and University of Georgia a minimum annual royalty. Under the license agreement, Emory and University of Georgia are primarily responsible for prosecuting all patents related to the amdoxovir technology. We agreed to reimburse Emory and University of Georgia for the patent prosecution costs they incur after the date of the license agreement. We have the right to pursue any actions against third parties for infringement of the amdoxovir technology at our expense. Upon the conclusion of any such infringement action we bring, we are entitled to offset unrecovered expenses incurred in connection with the infringement action against a percentage of the aggregate milestone payments and royalties owed to Emory and University of Georgia during the



time the infringement action was pending. In addition, we are obligated to defend, indemnify and hold harmless Emory, University of Georgia and certain of their representatives against any claims or losses incurred as a result of our manufacturing, testing, design, use and sale of products utilizing the amdoxovir technology. Emory and University of Georgia have the right to terminate the license agreement or to convert the exclusive license to a nonexclusive license in the event we do not satisfy certain milestone obligations. Emory and University of Georgia may also terminate the license agreement upon an uncured breach of the agreement by us. In the event of such termination or conversion, we will grant Emory and University of Georgia certain nonexclusive, royalty-free license rights in all intellectual property under our control relating to the amdoxovir technology necessary for the marketing of products incorporating the

amdoxovir technology. The termination of the license agreement or the conversion from an exclusive to a nonexclusive agreement could adversely affect our business.

BUKWANG PHARM. IND. CO., LTD.

In February 1998, we entered into a license agreement with Bukwang pursuant to which we received an exclusive license to all of Bukwang's rights to clevudine for use in the hepatitis B field as well as all other human antiviral applications. Bukwang obtained its rights to clevudine through an exclusive license from Yale University and University of Georgia. Our license includes all countries of the world except Korea. As consideration for the exclusive license of the clevudine technology, we paid a license initiation fee and agreed to pay development and sales milestones. We also agreed to pay a royalty on the net sales of any licensed products. Beginning the third year after the first FDA registration is granted for an FDA-approved product incorporating the clevudine technology, we will be required to pay an annual minimum royalty. Under the license agreement, Yale and University of Georgia are primarily responsible for prosecuting all patents related to the clevudine technology which they licensed to Bukwang, at our expense.

We are primarily responsible for prosecuting all patents related to any clevudine technology that may be acquired by Bukwang or us at our own expense. In addition, Yale and University of Georgia have the first right to pursue any actions against third parties for infringement of the clevudine technology, either jointly with us (with expenses shared equally) or, if not jointly with us, solely at their expense. Upon the conclusion of any infringement action we alone brought, we are entitled to offset unrecovered expenses incurred in connection with the infringement action against a percentage of the aggregate milestone payments and royalties owed to Bukwang during the time the infringement action is pending. We are obligated to indemnify Bukwang against any claims or losses incurred in connection with our breach of the license agreement or our manufacture, testing, design, use, sale and labeling of products utilizing the clevudine technology. Bukwang has the right to terminate the license agreement in the event we do not achieve milestone obligations or on an uncured breach of the agreement by us. In the event of termination by Bukwang for a failure to meet milestones or our breach of the agreement, we will grant Bukwang certain nonexclusive, royalty free license rights in all intellectual property under our control relating to the clevudine technology necessary for marketing products which contain clevudine. The termination of the license agreement could adversely affect our business.

DYNAVAX TECHNOLOGIES CORPORATION

In April 2000, our licensing and collaborative agreement with Dynavax to develop immunostimulatory pharmaceutical candidates for the prevention and/or treatment of serious viral diseases, became effective. Under this agreement, we purchased $2.0 million of Dynavax Series T Preferred Stock. The license agreement grants Triangle exclusive worldwide rights to Dynavax' ISS for the treatment of HIV and the prevention and treatment of hepatitis B infection and hepatitis C infection. With regard to the treatment of HIV, the license agreement does not include conjugated ISS, where the antigen is chemically bound to the ISS. We will collaborate with Dynavax in the development of immunostimulatory pharmaceutical candidates and we will be responsible for funding specific development activities, as well as paying development milestones and royalty payments. Under the agreement, we will indemnify Dynavax against any claim or loss resulting from our manufacture, testing, design, use, sale or labeling of products which use the technology licensed from Dynavax, except for claims or losses resulting from Dynavax' negligence, intentional misconduct or breach of contract. We and Dynavax have agreed to indemnify each other against any claims or losses resulting from a breach of our respective representations and warranties contained in the license agreement. If Dynavax

does not terminate an infringement by a third party of the licensed technology or does not bring suit to do so, we may pursue action for infringement. We may offset our expenses in bringing suit against a percentage of the royalty payments due to Dynavax under the agreement. Either party may



terminate the agreement if the other party has not corrected, or where correction in such timeframe is impossible, taken reasonable steps to correct, a material breach or default within 60 days of written notice of the breach or default from the other party.

TERMINATED LICENSE AND COLLABORATION AGREEMENTS

In June 1997, we entered into a license agreement with Mitsubishi Pharma Corporation pursuant to which we received an exclusive license to all of Mitsubishi's rights to Coactinon(R) for use in the HIV field in all countries expect Japan. In January 2002, we terminated this license agreement.

In August 1997, we acquired Avid Corporation by merger. Avid had worldwide license rights to mozenavir dimesylate for use in the HIV field pursuant to a license agreement with The Dupont Pharmaceuticals Company, now Bristol-Myers Squibb Company, BMS. Avid also had proprietary assays to screen compounds for the treatment of hepatitis B. In November 2001, we terminated the license agreement with BMS.

In July 2000, we entered into a licensing and collaborative agreement with Arrow Therapeutics Limited to identify and develop novel anti-viral agents for the treatment of hepatitis C virus. We terminated this agreement in September 2001.

PATENTS AND PROPRIETARY RIGHTS

Our success will depend on our ability and the ability of our licensors to obtain and maintain patents and proprietary rights for our drug candidates and to avoid infringing the proprietary rights of others, both in the United States and in foreign countries. We have no patents solely in our own name and we have a small number of patent applications of our own pending. We have two patent filings which are jointly owned with other entities. We have licensed or have an option to license, patents, patent applications and other proprietary rights from third parties for each of our drug candidates. If we breach our licenses we may lose rights to important technology and drug candidates.

The patents we have licensed covering the drug Coviracil will expire in the United States in 2015, and outside the United States in 2011-2012. The patents we have licensed covering the drug amdoxovir will expire in the United States in 2015 and outside the United States, if issued, in 2013. The patents that we have licensed covering the drug clevudine will expire in the United States in 2014 and outside the United States in 2015. These patents can expire earlier if they are allowed to abandon or are not adequately maintained. The patent terms of one United States patent covering each drug may be extended under the Patent Term Restoration Act to compensate for some amount of the time spent in the process of drug approval. We do not know the length of the patent-term extension that we may be granted on these drugs, if any.

Our patent position on some of our drug candidates, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or

have licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. If they do so successfully, rights we receive under those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes may infringe the patent rights of others.

Several pharmaceutical and biotechnology companies, universities and research institutions have filed patent applications or received patents that cover our technologies or technologies similar to ours. Others have filed patent applications and received patents that conflict with patents or patent applications we own or have licensed, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our drug candidates. For example, United States patent applications are confidential while pending in the Patent and Trademark Office and patent applications filed in foreign countries are often first published six months or more after filing. Any conflicts resulting from third party patent applications and patents could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If other companies obtain patents with conflicting claims, we may be required to obtain licenses to these



patents or to develop or obtain alternative technology. We may not be able to obtain any license on acceptable terms or at all. Any failure to obtain licenses could delay or prevent us from pursuing the development or commercialization of our drug candidates, which would adversely affect our ability to achieve profitability.

There are significant risks regarding the patent rights of one of our licensed drug candidates. We may not be able to commercialize amdoxovir due to patent rights held by third parties other than our licensors. Third parties have filed numerous patent applications and have received numerous issued patents in the United States and many foreign countries that relate to this drug candidate and its use alone or in combination to treat HIV and hepatitis B. As a result, our patent position regarding the use of amdoxovir to treat HIV and/or hepatitis B is highly uncertain and involves numerous complex legal and factual questions that are unknown or unresolved. If any of these questions is resolved in a manner that is not favorable to us, we would not have the right to commercialize amdoxovir in the absence of a license from one or more third parties, which may not be available on acceptable terms or at all. Even if any of these questions is resolved in our favor, we may still attempt to obtain licenses from one or more third parties to reduce the risks of challenges to our patent positions. These licenses may not be available on acceptable terms or at all.

With respect to any of our drug candidates, litigation, patent opposition and adversarial proceedings, including the currently pending proceedings, could result in substantial costs to us. The costs of the currently pending proceedings are significant and may increase significantly during the next several years. We anticipate that additional litigation and/or proceedings will be initiated to enforce any patents we own or license, or to determine the scope, validity and enforceability of our or other parties' proprietary rights and the priority of an invention. Any of these activities could result in substantial costs and/or delays to us. The outcome of any of these proceedings may significantly affect our rights to develop and commercialize drug candidates and technology.

United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. A court or

administrative body may not hold our licensed patents valid or may not find an alleged infringer to be infringing. Further, the license and option agreements with Emory, University of Georgia and Dynavax provide that each of these licensors is primarily responsible for any patent prosecution activities, such as litigation, patent conflict proceedings, patent opposition or other actions, for the technology licensed to us. These agreements also provide that we generally must reimburse these licensors for the costs they incur in performing these activities. Similarly, Yale and University of Georgia, the licensors of clevudine to Bukwang, are primarily responsible for patent prosecution activities with respect to clevudine at our expense. As a result, we generally do not have the ability to institute or determine the conduct of any patent proceedings unless our licensors elect not to institute or to abandon the proceedings. If our licensors elect to institute and prosecute patent proceedings, our rights will depend in part on the manner in which these licensors conduct the proceedings. In any proceedings they elect to initiate and maintain, these licensors may not vigorously pursue or defend or may decide to settle on terms that are unfavorable to us. An adverse outcome of these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using technology, any of which could adversely affect our business. Moreover, the mere uncertainty resulting from the initiation and continuation of any technology related litigation or adversarial proceeding could adversely affect our business pending resolution of the disputed matters.

We also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for any breach. Our trade secrets may also be independently discovered by competitors. We rely on technologies to which we do not have exclusive rights or which may not be patentable or proprietary and thus may be available to competitors. We have filed applications for, but have not obtained, trademark registrations for various marks in the United States and other jurisdictions. We have received U.S. trademark registrations for our corporate name and our corporate name and logo, as well as the mark Coviracil(R). We have received a Canadian trademark registration for the mark Coviracil(R). We have also received a registration in the European Union for our corporate logo. Our pending application in the European Union for the mark Coviracil(TM) has been opposed by Orsem, based on registrations for the mark Coversyl in various countries, and Les Laboratories Serveir, based on a French registration for the mark Coversyl. We do not believe that the marks Coviracil and Coversyl are confusingly similar, but, in the event they are found to be confusingly similar, we may need to adopt a different product name for emtricitabine in the applicable jurisdictions.



Several other companies use trade names that are similar to our name for their businesses. If we are unable to obtain any licenses that may be necessary for the use of our corporate name, we may be required to change our name. Our management personnel were previously employed by other pharmaceutical companies. The prior employers of these individuals may allege violations of trade secrets and other similar claims relating to their drug development activities for us.

GOVERNMENT REGULATION

The development of our drug candidates and the manufacturing and marketing of any drug candidates we successfully develop are subject to extensive regulation by numerous governmental authorities in the United States and other countries.

FDA APPROVAL

In the United States, pharmaceuticals are subject to rigorous FDA regulation. The Federal Food, Drug, and Cosmetic Act governs the testing, manufacture, approval, labeling, storage, record keeping, reporting, advertising and promotion of our drug candidates and any products that we may successfully develop. Product development and approval within this regulatory framework takes a number of years and involves the expenditure of substantial resources. The steps required before a new prescription drug may be marketed in the United States include:

- preclinical laboratory and animal tests,
- the submission to the FDA of an IND, which must be evaluated and found acceptable by the FDA before human clinical trials may commence,
- adequate and well-controlled human clinical trials to establish the safety and effectiveness of the drug,
- the submission of an NDA to the FDA,
- FDA review of the NDA, which usually includes review by an Advisory Committee to the FDA, and
- FDA approval of the NDA.

Prior to obtaining FDA approval of an NDA, the facilities that will be used to manufacture the drug must undergo a preapproval inspection to ensure compliance with good manufacturing practices regulations. A company must also pay a one-time user fee for each NDA submission and pay annual user fees for each approved product and manufacturing establishment.

Preclinical tests include laboratory evaluation of the drug candidate and animal studies to assess the safety and effectiveness of the drug candidate and its formulation. Preclinical test results are submitted to the FDA as part of an IND, and unless the FDA objects, the IND will become effective 30 days following its receipt. If the FDA has concerns about a proposed clinical trial, it may delay the trial and require modifications to the trial protocol before permitting the trial to begin. There are no guarantees that the FDA will permit a proposed IND to become effective.

Clinical trials involve administering a drug candidate to normal, healthy volunteers or to patients identified as having the condition for which the drug candidate is being tested. The drug candidate is administered under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols previously submitted to the FDA as part of the IND. These protocols detail the objectives of the trial, the parameters used to monitor safety and the efficacy criteria that are being evaluated. Each clinical trial is conducted under the auspices of a local Institutional Review Board which considers among other things:

- the clinical trial plan,
- ethical factors,
- safety of the human subjects, and
- possible liability risk for the institution.



Clinical trials are typically conducted in three sequential phases that may overlap.

- Phase I involves the initial closely monitored introduction of the drug candidate in normal volunteers or patients, where the emphasis is on testing for safety (adverse effects), dosage tolerance,

metabolism, distribution, excretion, clinical pharmacology and early evidence of effectiveness.

- Phase II involves trials in a limited patient population to determine the effectiveness of the drug candidate for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible short-term side effects and safety risks. After a drug candidate demonstrates an acceptable safety profile and probable effectiveness, Phase III trials are initiated.

- Phase III trials are undertaken to further evaluate clinical effectiveness and to further test for safety within an expanded patient population at multiple clinical study sites.

Pivotal clinical trials are those expanded studies intended to support a submission for regulatory approval of a drug candidate. Pilot clinical trials are those involving a small number of patients. The FDA reviews both the clinical trial plans and the results of the trials at each phase, and any safety reports and other information submitted during the clinical trial. The FDA may discontinue the trials at any time if there are significant safety issues.

The results of the preclinical tests and clinical trials are submitted to the FDA in the form of an NDA for marketing approval. The testing and approval process requires substantial time and effort and approvals may not be granted on a timely basis or at all. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review process and may delay marketing approval. Upon approval, a drug may be marketed only for the approved indications in the approved dosage forms. Further clinical trials are required to gain approval for the use of the product for any additional indications or dosage forms. The FDA may also require post-marketing testing, such as monitoring for adverse effects, which can involve significant expense.

A company may conduct clinical trials outside of the United States, using a product manufactured outside the country, and in some circumstances manufactured within the United States, without an IND. The FDA will accept data from foreign clinical trials to support clinical investigations in the United States and/or approval of an NDA only if the agency determines that the trials are well-designed, well-conducted, performed by qualified investigators, and conducted in accordance with internationally recognized ethical principles and any applicable foreign requirements. We may, in the future, conduct clinical trials with other drug candidates in various foreign countries without an IND and have done so in the case of clevudine. Clinical trials we conduct in either the United States or foreign countries may not demonstrate that any of our drug candidates under development are safe and effective, and the FDA may require additional clinical trials to support approval of an NDA.

As part of its IND regulations, the FDA has developed several regulatory procedures to accelerate the clinical testing and approval of drugs intended to treat life-threatening or seriously debilitating illnesses under certain circumstances. For example, in 1988, the FDA issued regulations to expedite the development, evaluation and marketing of drugs for life-threatening and severely debilitating illnesses, especially where no alternative therapy exists. These procedures encourage early consultation between the IND sponsors and the FDA in the preclinical testing and clinical trial phases to determine what evidence will be necessary for marketing approval and to assist the sponsors in designing clinical trials. Under this program, the FDA works closely with the IND sponsors to accelerate and condense Phase II clinical trials, which may, in some cases, either eliminate the need to conduct Phase III trials or limit the scope of Phase III trials. Under these regulations, the FDA may require post-marketing

(Phase IV) clinical trials to obtain additional information on the drug's risks, benefits and optimal use.

The FDA has also issued regulations establishing an accelerated NDA approval procedure for certain drugs under Subpart H of the agency's NDA approval regulations. The Subpart H regulations provide for accelerated NDA approval for new drugs intended to treat serious or life-threatening diseases where the drugs provide a meaningful therapeutic advantage over existing treatment. Under this accelerated approval procedure, the FDA may approve a drug based on evidence from adequate and well-controlled studies of the drug's effect on a surrogate endpoint that is reasonably likely to predict clinical benefits, or on evidence of the drug's effect on a clinical



endpoint other than survival or irreversible morbidity. This approval is conditional on the favorable completion of post-marketing (Phase IV) trials to establish and define the degree of clinical benefits to the patient. These clinical trials would usually be underway when the product obtains this accelerated approval. The FDA may also impose distribution restrictions where necessary to assure safe use of the drug. If, after approval, a post-marketing clinical study establishes that the drug does not perform as expected, or if post-marketing restrictions are not adhered to or are not adequate to ensure the safe use of the drug, or other evidence demonstrates that the product is not safe and/or effective under its conditions of use, the FDA may withdraw approval. The Subpart H accelerated approval regulations can complement other accelerated approval regulations. These two procedures for expediting the clinical evaluation and approval of certain drugs may shorten the drug development process by as much as two to three years.

The Food and Drug Administration Modernization Act of 1997 also contains statutory provisions designed to expedite the review of new drugs intended to treat serious or life-threatening conditions. This Act amended the Federal Food, Drug, and Cosmetic Act to provide for the designation of a "fast track" product. This Act also establishes procedures to facilitate development and expedite FDA review of a drug intended for treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs. Approval of a fast track product may be subject to conditions, including requirements to conduct post-approval clinical trials and to presubmit promotional materials. Approval of a fast track product can be withdrawn, using expedited procedures, for reasons similar to those specified in the Subpart H Regulations.

Once the sale of a product is approved, the FDA regulates the manufacturing, marketing, safety reporting and other activities. The FDA periodically inspects both domestic and foreign drug manufacturing facilities to ensure compliance with applicable good manufacturing practice regulations, NDA conditions of approval and other requirements. In addition, manufacturers must register with the FDA and submit a list of every drug in commercial distribution. We do not have or currently intend to develop the facilities to manufacture our drug candidates in commercial quantities and, therefore, we intend to establish relationships with contract manufacturers for the commercial manufacture of any products that we successfully develop. Some of these contract manufacturers may be located outside the United States. Our contract manufacturers may not be able to attain or maintain compliance with good manufacturing practice regulations and NDA conditions. Changes in contract manufacturers may result in the need for new NDA submissions or delays in the availability of product. Post-marketing reports are also required, for purposes such as monitoring the product's usage and any adverse effects. Product approvals may be withdrawn, or other actions may be ordered, or criminal or

other sanctions imposed if we do not maintain compliance with regulatory requirements.

FOREIGN REGULATORY APPROVAL AND SALE

Many foreign countries also regulate the clinical testing, manufacturing, reporting, marketing and use of pharmaceutical products. The requirements relating to the conduct of clinical trials, product approval, manufacturing, marketing, pricing and reimbursement vary widely from country to country and we can give no assurance that Triangle or any third parties with whom we may establish collaborative relationships will be able to attain or maintain compliance with such requirements.

In addition to the import requirements of foreign countries, a company must also comply with United States laws governing the export of FDA regulated products. Pursuant to the FDA Export Reform and Enhancement Act of 1996, a drug that has not obtained FDA approval may be exported to any country in the world without FDA authorization if the product both complies with the laws of the importing country and has obtained valid marketing authorization in one of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union, or a country in the European Economic Area. The FDA is authorized to add countries to this list in the future. Among other restrictions, a drug that has not obtained FDA approval may be exported under the new law only if it is not adulterated, accords to the specifications of the foreign purchaser, complies with the laws of the importing country, is labeled for export, is manufactured in substantial compliance with good manufacturing practice regulations and is not sold in the United States.



OTHER REGULATIONS

In addition to regulations enforced by the FDA, we are also subject to regulation under:

- the Occupational Safety and Health Act,
- the Controlled Substances Act,
- the Toxic Substances Control Act,
- the Resource Conservation and Recovery Act, and
- other similar federal, state and local regulations governing permissible laboratory activities, waste disposal, handling of toxic, dangerous or radioactive materials and other matters.

We believe we are in compliance, in all material respects, with all applicable regulations. These regulations are subject to change and may in the future require substantial effort and cost to us to comply with each of the regulations, and may possibly restrict our business activities.

COMPETITION

We are engaged in segments of the drug industry that are highly competitive and rapidly changing. Any of our current drug candidates that we successfully develop will compete with numerous existing therapies. In addition, many companies are pursuing novel drugs that target the same diseases we are targeting. We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV and hepatitis B. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors' products may be more effective, or more effectively marketed and sold, than any of our products. Competitive products may render our products

obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of a cure or new treatment methods for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. Many of our competitors:

- have significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products,
- have extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products, and
- have products that have been approved or are in late stage development and operate large, well-funded research and development programs.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations are also becoming increasingly aware of the commercial value of their inventions and are more actively seeking to commercialize the technology they have developed.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability of supply, marketing and sales capability, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could hurt our competitive position and adversely affect our business.

MANUFACTURING

We do not have any internal manufacturing capacity and we rely on third party manufacturers for the manufacture of all of our clinical trial material. We plan to use our existing relationships or to establish relationships with additional third party manufacturers for products that we develop. The terms of the Abbott Alliance provide that Abbott will manufacture all or a portion of our product requirements for those products that are or become covered by the Abbott Alliance. We may be unable to maintain our relationship with Abbott or to



establish or maintain relationships with other manufacturers on acceptable terms, and manufacturers may be unable to manufacture products in commercial quantities on a cost effective basis. Our dependence on third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and commercialize products on a timely and competitive basis. Further, third party manufacturers may encounter manufacturing or quality control problems in manufacturing our products and may be unable to maintain the necessary governmental licenses and approvals to continue manufacturing our products. Our business could be adversely affected if we fail to establish or maintain relationships with third parties for our manufacturing requirements on acceptable terms.

SALES AND MARKETING

In the United States, we currently intend to market the drug candidates covered by the Abbott Alliance in collaboration with Abbott and to market other

drug candidates that we successfully develop, that do not become part of the Abbott Alliance, through a small sales force or through arrangements or collaborations with third parties. Outside of the United States, we expect Abbott to market drug candidates covered by the Abbott Alliance and, for any other drug candidates that we successfully develop that do not become part of the Abbott Alliance, we intend to market and sell through arrangements or collaborations with third parties. In addition, we expect Abbott to handle the distribution and sale of drug candidates covered by the Abbott Alliance both inside and outside the United States. With respect to the United States, our ability to market the products that we successfully develop may be contingent on recruitment, training and deployment or outsourcing of a sales and marketing force as well as the performance of Abbott under the Abbott Alliance. We may be unable to establish marketing or sales capabilities or to maintain arrangements or enter into new arrangements with third parties to perform those activities on favorable terms. In addition, third parties may have significant control or influence over important aspects of the commercialization of our drug candidates, including market identification, marketing methods, pricing, composition of sales force and promotional activities. We may have limited control over the amount and timing of resources that a third party devotes to our products. Our business may never achieve profitability if we fail to establish or maintain a sales force and marketing, sales and distribution capabilities.

HEALTH CARE REFORM MEASURES AND THIRD PARTY REIMBURSEMENT

The efforts of governments and third party payors to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A number of legislative and regulatory proposals to change the health care system have been considered in recent years. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on drug pricing. Legislative or regulatory proposals or changes in managed care systems may be adopted that may have a negative effect on our business. The announcement and/or adoption of proposals could have an adverse effect on our ability to earn profits and financial condition. Sales of prescription drugs depend significantly on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. These third party payors frequently require that drug companies give them predetermined discounts from list prices, and they are increasingly challenging the prices for medical products and services. Present combination treatment regimens for the treatment of HIV are expensive and costs may increase as new combinations are developed. These costs have resulted in limitations in the reimbursement available from third party payors for the treatment of HIV infection, and we expect these limitations will continue in the future. Third party payors may not consider products we may bring to the market cost effective and may not reimburse the consumer sufficiently to allow us to sell our products on a profitable basis.

HUMAN RESOURCES

As of December 31, 2001, Triangle had approximately 115 employees, including approximately 85 in development and approximately 30 in administration. Of these employees, 44 hold advanced degrees, of which 27 are M.D.s or Ph.D.s. In addition, we routinely engage the services of contractors and consultants to supplement our employees in the completion of our normal business operations. Our future success will depend in large part upon our ability to attract and retain highly qualified personnel. Due to the unexpected death of Dr. David W. Barry, we are currently conducting a search to fill the position of chief executive officer. Our employees are not represented by any collective bargaining agreements, and we have never experienced a work stoppage. All of our employees have signed confidentiality agreements and certain of our employees, including all of our officers, have entered into employment agreements.

RISK AND UNCERTAINTIES

IN ADDITION TO THE OTHER INFORMATION CONTAINED HEREIN, THE FOLLOWING RISKS AND UNCERTAINTIES SHOULD BE CAREFULLY CONSIDERED IN EVALUATING TRIANGLE AND ITS BUSINESS.

ALL OF OUR DRUG CANDIDATES ARE IN DEVELOPMENT AND WE MAY NEVER SUCCESSFULLY COMMERCIALIZE THEM.

Some of our drug candidates are at an early stage of development and all of our drug candidates will require expensive and lengthy testing and regulatory clearances before we may commercialize them. We do not expect any of our drug candidates to be commercially available before the year 2003. There are many reasons that we may fail in our efforts to develop our drug candidates, including that:

- our drug candidates may be ineffective, toxic or may not receive regulatory clearances,
- our drug candidates may be too expensive to manufacture or market or may not achieve broad market acceptance,
- third parties may hold proprietary rights that preclude us from developing or marketing our drug candidates, or
- third parties may market equivalent or superior products.

The success of our business depends on our ability to successfully develop and market our drug candidates.

WE HAVE INCURRED LOSSES SINCE INCEPTION AND MAY NEVER ACHIEVE PROFITABILITY.

We formed Triangle in July 1995 and have incurred losses since our inception. At December 31, 2001, our accumulated deficit was $406.9 million. Our historical costs relate primarily to the acquisition and development of our drug candidates and selling, general and administrative costs. We have not generated any revenue from the sale of our drug candidates to date, and do not expect to do so before the year 2003. In addition, we expect annual losses to continue over the next several years as a result of our drug development and commercialization efforts. To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any products we develop. We may never generate significant revenue or achieve profitability.

IF WE NEED ADDITIONAL FUNDS AND ARE UNABLE TO RAISE THEM, WE WILL HAVE TO CURTAIL OR CEASE OPERATIONS.

Our drug development programs and our efforts to commercialize our drug candidates require substantial working capital, including expenses for:

- preclinical testing,
- chemical synthetic scale-up,
- manufacture of drug substance for clinical trials,
- toxicology studies,
- clinical trials of drug candidates,
- sales and marketing,
- payments to our licensors, and
- potential commercial launch of our drug candidates.

Our future working capital needs will depend on many factors, including:

- the progress, magnitude and success of our drug development programs,
- the scope and results of preclinical testing and clinical trials,
- the cost, timing and outcome of regulatory filings and reviews,
- the costs under current and future license and option agreements for our drug candidates, including the costs of obtaining and enforcing patent protection for our drug candidates,



- the costs of acquiring any additional drug candidates,
- the out-licensing of existing drug candidates,
- the rate of technological advances by us and other companies,
- the commercial potential of our drug candidates,
- the magnitude of our administrative and legal expenses,
- the costs of establishing sales and marketing functions, and
- the costs of establishing third party arrangements for manufacturing.

We have incurred negative cash flow from operations since we incorporated Triangle and do not expect to generate positive cash flow from our operations for at least the next several years. We believe that our existing cash, cash equivalents and investments, considering our recent steps to reduce cash usage and completed financings, will be adequate through the second quarter of 2003. We expect that we will need additional future financings to fund our operations. We may not be able to obtain adequate financing to fund our operations, and any additional financing we obtain may be on terms that are not favorable to us. In addition, we may not receive the contingent development milestone payments under the Abbott Alliance. In addition, any future financings could substantially dilute our stockholders. If adequate funds are not available, we will be required to delay, reduce or eliminate one or more of our drug development programs, to enter into new collaborative arrangements or to modify the Abbott Alliance on terms that may not be favorable to us. These collaborative arrangements or modifications could result in the transfer of valuable rights to third parties. In addition, we may acquire technologies and drug candidates that would increase our working capital requirements.

PROJECTED DEVELOPMENT COSTS ARE DIFFICULT TO ESTIMATE AND MAY CHANGE FREQUENTLY PRIOR TO REGULATORY APPROVAL.

While all new compounds require standard regulated phases of testing, the actual type and scope of testing can vary significantly among different drug candidates which may result in significant disparities in the total costs required to complete the respective development programs.

The number and type of studies that may be required by the FDA for a particular compound are based on the compound's clinical profile compared to existing therapies for the targeted patient population. Factors that affect the costs of a clinical trial include:

- the number of patients required to participate in clinical trials to demonstrate statistical significance for a drug's safety and efficacy,
- the time required to enroll the targeted number of patients in clinical trials, which may vary depending on the size and availability of the targeted patient population and the perceived benefit to study participants, and
- the number and type of required laboratory tests supporting clinical trials.

Other activities required before filing an NDA include regulatory preparation for submission, biostatistical analyses, scale-up synthesis, and the production of a required amount of commercial grade drug product inventory which meets current Good Manufacturing Practice standards.

In addition, ongoing development programs and associated costs are subject to frequent, significant and unpredictable changes due to a number of factors, including:

- data collected in preclinical or clinical studies may prompt significant changes or enhancements to an ongoing development program,
- the FDA may direct the sponsor to change or enhance its ongoing development program based on developments in the testing of similar compounds or related compounds,
- unexpected regulatory requirements or interim reviews by regulatory agencies may cause delays or changes to development programs, and
- anticipated manufacturing costs may change significantly due to required changes in manufacturing processes or variances from anticipated manufacturing process yields.



BECAUSE WE MAY NOT SUCCESSFULLY COMPLETE CLINICAL TRIALS REQUIRED FOR REGULATORY APPROVAL OF OUR DRUG CANDIDATES, OUR BUSINESS MAY NEVER ACHIEVE PROFITABILITY.

No regulatory authority has approved any of our drug candidates. To obtain regulatory approvals needed for the sale of our drug candidates, we must demonstrate through preclinical testing and clinical trials that each drug candidate is safe and effective. The clinical trial process is complex and uncertain and the regulatory environment varies widely from country to country. Positive results from preclinical testing and early clinical trials do not ensure positive results in pivotal clinical trials. Many companies in our industry have suffered significant setbacks in pivotal clinical trials, even after promising results in earlier trials. Any of our drug candidates may produce undesirable side effects in humans. These side effects, or side effects from other drugs in a trial, could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a drug candidate, as occurred with our study FTC-302 in South Africa, or could result in regulatory authorities refusing to approve the drug candidate for any and all targeted indications. We, the FDA, or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks.

CLINICAL TRIALS MAY TAKE LONGER TO COMPLETE AND COST MORE THAN WE EXPECT, WHICH WOULD ADVERSELY AFFECT OUR ABILITY TO COMMERCIALIZE DRUG CANDIDATES AND ACHIEVE PROFITABILITY.

Clinical trials are lengthy and expensive. They require adequate supplies of drug substance and sufficient patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population,
- the nature of the protocol,
- the proximity of patients to clinical sites,
- the eligibility criteria for the clinical trial, and
- the perceived benefit of participating in a clinical trial.

Delays in patient enrollment can result in increased costs and longer

development times. Even if we successfully complete clinical trials, we may not be able to file any required regulatory submissions in a timely manner and we may not receive regulatory approval for the drug candidate. In addition, if the FDA or foreign regulatory authorities require additional clinical trials we could face increased costs and significant development delays.

We conduct clinical trials in many countries around the world and are subject to the risks and uncertainties of doing business internationally. Disruptions in communication and transportation, civil unrest and currency exchange rates may affect the time and costs required to complete clinical trials in other countries.

Changes in regulatory policy or new regulations could also result in delays or rejections of our applications for approval of our drug candidates. Drug candidates designated as "fast track" products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

IF WE OR OUR LICENSORS ARE NOT ABLE TO OBTAIN AND MAINTAIN ADEQUATE PATENT PROTECTION FOR OUR DRUG CANDIDATES, WE MAY BE UNABLE TO COMMERCIALIZE OUR DRUG CANDIDATES OR PREVENT OTHER COMPANIES FROM USING OUR TECHNOLOGY IN COMPETITIVE PRODUCTS.

Our success will depend on our ability and the ability of our licensors to obtain and maintain patents and proprietary rights for our drug candidates and to avoid infringing the proprietary rights of others, both in the United States and in foreign countries. We have no patents solely in our own name and we have a small number of patent applications of our own pending. We have two patent filings which are jointly owned with other entities. We have licensed, or have an option to license, patents, patent applications and other proprietary rights from third parties for each of our drug candidates. If we breach our licenses we may lose rights to important technology and drug candidates.



Our patent position on some of our drug candidates, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or have licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. If they do so successfully, rights we receive under those patents may not provide competitive advantages to us. Further, the manufacture, use or sale of our products or processes may infringe the patent rights of others.

Several pharmaceutical and biotechnology companies, universities and research institutions have filed patent applications or received patents that cover our technologies or technologies similar to ours. Others have filed patent applications and received patents that conflict with patents or patent applications we own or have licensed, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our drug candidates. For example, United States patent applications are confidential while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published six months or more after filing.

Any conflicts resulting from third party patent applications and patents could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If other companies obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any license on acceptable terms or at all. Any failure to obtain licenses could delay or prevent us from pursuing the development or commercialization of our drug candidates, which would adversely affect our ability to achieve profitability.

There are significant risks regarding the patent rights of one of our licensed drug candidates. We may not be able to commercialize amdoxovir due to patent rights held by third parties other than our licensors. Third parties have filed numerous patent applications and have received numerous issued patents in the United States and many foreign countries that relate to this drug candidate and its use alone or in combination to treat HIV and hepatitis B. As a result, our patent position regarding the use of amdoxovir to treat HIV and/or hepatitis B is highly uncertain and involves numerous complex legal and factual questions that are unknown or unresolved. If any of these questions is resolved in a manner that is not favorable to us, we would not have the right to commercialize amdoxovir in the absence of a license from one or more third parties, which may not be available on acceptable terms or at all. Even if any of these questions is resolved in our favor, we may still attempt to obtain licenses from one or more third parties to reduce the risks of challenges to our patent positions. These licenses may not be available on acceptable terms or at all.

There are also risks regarding our rights to Coviracil. We license our rights to Coviracil from Emory. Emory and Shire Pharmaceuticals have been disputing several issues related to the rights to Coviracil. Shire Pharmaceuticals recently announced an agreement as to material terms of a settlement with Glaxo and Emory regarding these disputes. This settlement has not been finalized and the definitive settlement may differ from the material terms disclosed.

AMDOXOVIR (FORMERLY KNOWN AS DAPD)

We obtained our rights to amdoxovir under a license from Emory and the University of Georgia. Our rights to amdoxovir include a number of issued United States patents that cover:

- composition of matter,
- a method for the synthesis of amdoxovir,
- methods for the use of amdoxovir alone or in combination with several other agents for the treatment of hepatitis B, and
- a method to treat HIV with amdoxovir.

We also have rights to several foreign patents and patent applications that cover methods for the use of amdoxovir alone or in combination with other anti-hepatitis B agents for the treatment of hepatitis B. Additional foreign patent applications are pending which contain claims for the use of amdoxovir to treat HIV. Emory and the University of Georgia filed patent applications claiming these inventions in the United States in 1990 and 1992.

Shire Pharmaceuticals filed a patent application in the United States in 1988 on a group of nucleosides in the same general class as amdoxovir and their use to treat HIV, and has filed corresponding patent applications in foreign countries. The Patent and Trademark Office issued a patent to Shire Pharmaceuticals in 1993 covering a class of nucleosides that includes amdoxovir and its use to treat HIV. Corresponding patents have been issued to Shire Pharmaceuticals in many foreign countries. Emory has filed an opposition to patent claims granted to Shire

Pharmaceuticals by the European Patent Office based, in part, on Emory's assertion that Shire Pharmaceuticals' patent does not disclose how to make amdoxovir. In a patent opposition hearing held at the European Patent Office on March 4, 1999, the Opposition Division ruled that the Shire Pharmaceuticals European patent covering amdoxovir is valid. Emory has appealed this decision to the European Patent Office Technical Board of Appeal. If the Technical Board of Appeal affirms the decision of the Opposition Division, or if we or Emory do not pursue the appeal, we would not be able to sell amdoxovir in Europe without a license from Shire Pharmaceuticals, which may not be available on acceptable terms or at all. Shire Pharmaceuticals has opposed patent claims granted to Emory on both amdoxovir and DXG, the parent drug into which amdoxovir is converted in the body, in the Australian Patent Office.

In a decision dated November 8, 2000, the Australian Patent Office held that Emory's patent claims directed to amdoxovir are not patentable over an earlier Shire Pharmaceuticals patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory, the University of Georgia or we are unsuccessful in the appeal, then we will not be able to sell amdoxovir in Australia without a license from Shire Pharmaceuticals, which may not be available on acceptable terms or at all. Shire Pharmaceuticals' opposition to Emory's patent claims on DXG in Australia is ongoing. If Emory, the University of Georgia or we do not challenge, or are not successful in any challenge to, Shire Pharmaceuticals' issued patents, pending patent applications, or patents that may issue from its applications, we will not be able to manufacture, use or sell amdoxovir in the United States and any foreign countries in which Shire Pharmaceuticals receives a patent without a license from Shire Pharmaceuticals. We may not be able to obtain a license from Shire Pharmaceuticals on acceptable terms or at all.

IMMUNOSTIMULATORY SEQUENCE PRODUCT CANDIDATES

In March 2000, we entered into a licensing and collaborative agreement with Dynavax to develop immunostimulatory polynucleotide sequence product candidates for the prevention and/or treatment of serious viral diseases, which became effective in April 2000. ISS are polynucleotides which stimulate the immune system, and could potentially be used in combination with our small molecule product candidates to increase the body's ability to defend against viral infection. ISS can be stabilized for use through internal linkages that do not occur in nature, including phosphorothioate linkages.

There are a number of companies which have patent applications and issued patents, both in the United States and in other countries, that cover ISS and their uses. Coley Pharmaceuticals, Inc. has filed several patent applications in this area and has in addition exclusively licensed a number of patent applications on this subject from the University of Iowa and Isis Pharmaceuticals, Inc. A number of these patent applications have been issued. A number of companies have also filed patent applications and have or are expected to receive patents on a number of polynucleotides and methods for their use and manufacture. These patents, if granted, could prevent us from making, using or selling any ISS that is covered by a patent issued to a third party unless we obtain a license from that party which may not be available on acceptable terms or at all.

With respect to any of our drug candidates, litigation, patent opposition and adversarial proceedings, including the currently pending proceedings, could result in substantial costs to us. The costs of the currently pending proceedings are significant and may increase significantly during the next several years. We anticipate that additional litigation and/or proceedings will be initiated to enforce any patents we own or license, or to determine the

scope, validity and enforceability of our or other parties' proprietary rights and the priority of an invention. Any of these activities could result in substantial costs and/or delays to us. The outcome of any of these proceedings may significantly affect our rights to develop and commercialize drug candidates and technology.

United States patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. A court or administrative body may not hold our licensed patents valid or may not find an alleged infringer to be infringing. Further, the license and option agreements with Emory, the University of Georgia and Dynavax provide that each of these licensors is primarily responsible for any patent prosecution activities, such as litigation, patent conflict proceeding, patent opposition or other actions, for the technology licensed to us. These agreements also provide that we generally must reimburse these licensors for the costs they incur in performing these activities. Similarly, Yale and the University of Georgia, the licensors of clevudine to Bukwang, are primarily responsible for patent prosecution activities with respect to clevudine at our expense. As a result, we generally do not have the ability to institute or determine the conduct of any patent proceedings unless our licensors elect not to



institute or to abandon the proceedings. If our licensors elect to institute and prosecute patent proceedings, our rights will depend in part on the manner in which these licensors conduct the proceedings. In any proceedings they elect to initiate and maintain, these licensors may not vigorously pursue or defend or may decide to settle on terms that are unfavorable to us. An adverse outcome of these proceedings could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using technology, any of which could adversely affect our business. Moreover, the mere uncertainty resulting from the initiation and continuation of any technology related litigation or adversarial proceeding could adversely affect our business pending resolution of the disputed matters.

BECAUSE WE MAY NOT BE ABLE TO MAINTAIN THE CONFIDENTIALITY OF OUR TRADE SECRETS AND KNOW-HOW, WE MAY LOSE A COMPETITIVE ADVANTAGE.

We also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for any breach. Our trade secrets may also be independently discovered by competitors. We rely on technologies to which we do not have exclusive rights or which may not be patentable or proprietary and may be available to competitors. We have filed applications for, but have not obtained, trademark registrations for various marks in the United States and other jurisdictions. We have received U.S. trademark registrations for our corporate name and our corporate name and logo, as well as the mark Coviracil(R). We have received a Canadian trademark registration for the mark Coviracil(R). We have also received a registration in the European Union for our corporate logo. Our pending application in the European Union for the mark Coviracil(TM) has been opposed by Orsem, based on registrations for the mark Coversyl in various countries, and Les Laboratories Serveir, based on a French registration for the mark Coversyl. We do not believe that the marks Coviracil and Coversyl are confusingly similar, but, in the event they are found to be confusingly similar, we may need to adopt a different product name for emtricitabine in the applicable jurisdictions. Several other companies use trade names that are similar to our name for their businesses. If we are unable to obtain any licenses that may be necessary for the use of our corporate name, we may be required to change our name. Our management personnel

were previously employed by other pharmaceutical companies. The prior employers of these individuals may allege violations of trade secrets and other similar claims relating to their drug development activities for us.

THE COSTS AND TIME REQUIRED TO COMPLY WITH EXTENSIVE GOVERNMENT REGULATIONS COULD PREVENT OR DELAY THE COMMERCIALIZATION OF OUR DRUG CANDIDATES.

In addition to preclinical testing, clinical trials and other approval procedures for human pharmaceutical products, we are subject to numerous domestic and international regulations covering the development and registration of pharmaceutical products. These regulations affect:

- manufacturing,
- safety,
- labeling,
- storage,
- record keeping,
- reporting, and
- marketing and promotion.

We must also comply with regulations governing non-clinical and clinical laboratory practices, safe working conditions, and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents we use in connection with our development work. The requirements vary widely from country to country and some requirements may vary from state to state in the United States. We expect the process of obtaining these approvals and complying with appropriate government regulations to be time consuming and expensive. Even if our drug candidates receive regulatory approval, we may still face difficulties in marketing and manufacturing those drug candidates. Any approval may be contingent on postmarketing studies or other conditions. The approval of any of our drug candidates may limit the indicated uses of the drug candidate. A marketed product, its manufacturer and the manufacturer's facilities are subject to continual review and periodic



inspections. The discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. The failure to comply with applicable regulatory requirements can, among other things, result in:

- fines,
- suspended regulatory approvals,
- refusal to approve pending applications,
- refusal to permit exports from the United States,
- product recalls,
- seizure of products,
- injunctions,
- operating restrictions, and
- criminal prosecutions.

In addition, adverse clinical results by others could negatively impact the development and approval of our drug candidates. Some of our drug candidates are intended for use as combination therapy with one or more other drugs, and adverse safety, effectiveness or regulatory developments in connection with the other drugs will also have an adverse effect on our business.

INTENSE COMPETITION MAY RENDER OUR DRUG CANDIDATES NONCOMPETITIVE OR OBSOLETE.

We are engaged in segments of the drug industry that are highly competitive and rapidly changing. Any of our current drug candidates that we successfully develop will compete with numerous existing therapies. In addition, many companies are pursuing novel drugs that target the same diseases we are targeting. We believe that a significant number of drugs are currently under development and will become available in the future for the treatment of HIV and hepatitis B. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors' products may be more effective, or more effectively marketed and sold, than any of our products. Competitive products may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of a cure or new treatment methods for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. Many of our competitors:

- have significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and market products,
- have extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products, and
- have products that have been approved or are in late stage development and operate large, well-funded research and development programs.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations are also becoming increasingly aware of the commercial value of their inventions and are more actively seeking to commercialize the technology they have developed.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many factors including:

- the safety and effectiveness of our products,
- the timing and scope of regulatory approvals,
- the availability of supply,
- marketing and sales capability,
- reimbursement coverage,
- price, and
- patent position.



Our competitors may develop or commercialize more effective or more affordable products, or obtain more effective patent protection, than we do. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which could hurt our competitive position.

IF OUR LICENSORS TERMINATE THEIR AGREEMENTS WITH US, WE COULD LOSE OUR RIGHTS TO OUR DRUG CANDIDATES.

We have licensed or obtained an option to license our drug candidates under agreements with our licensors. These agreements permit our licensors to terminate the agreements in circumstances such as our failure to achieve development milestones or the occurrence of an uncured material breach by us. The termination of any of these agreements would result in the loss of our rights to a drug candidate. On the termination of most of our license agreements, we are required to return the licensed technology to our licensors.

In addition, most of these agreements provide that we generally must reimburse our licensors for the costs they incur in performing any patent prosecution activities such as litigation, patent conflict, patent opposition or other actions, for the technology licensed to us. We believe that these costs as well as other costs under our license and option agreements will be substantial and may increase significantly during the next several years. Our inability or failure to pay any of these costs with respect to any drug candidate could result in the termination of the license or option agreement for the drug candidate.

IF WE ARE NOT ABLE TO SUCCESSFULLY MANUFACTURE OUR DRUG CANDIDATES, OUR BUSINESS MAY NEVER ACHIEVE PROFITABILITY.

We do not have any internal manufacturing capacity and we rely on third party manufacturers for the manufacture of all of our clinical trial material. We plan to use our existing relationships or to establish relationships with additional third party manufacturers for products that we develop. The terms of the Abbott Alliance provide that Abbott will manufacture all or a portion of our product requirements for those products that are or become covered by the Abbott Alliance. We may be unable to maintain our relationship with Abbott or to establish or maintain relationships with other manufacturers on acceptable terms, and manufacturers may be unable to manufacture products in commercial quantities on a cost effective basis. Our dependence on third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and commercialize products on a timely and competitive basis. Further, third party manufacturers may encounter manufacturing or quality control problems in manufacturing our products and may be unable to maintain the necessary governmental licenses and approvals to continue manufacturing our products.

BECAUSE WE DEPEND ON THIRD PARTIES, WE MAY BE UNABLE TO SUCCESSFULLY MARKET, SELL OR DISTRIBUTE PRODUCTS WE DEVELOP.

In the United States, we currently intend to market the drug candidates covered by the Abbott Alliance in collaboration with Abbott and to market other drug candidates that we successfully develop, that do not become part of the Abbott Alliance, through a small sales force or through arrangements or collaborations with third parties. Outside of the United States, we expect Abbott to market drug candidates covered by the Abbott Alliance and, for any other drug candidates that we successfully develop that do not become part of the Abbott Alliance, we intend to market and sell through arrangements or collaborations with third parties. In addition, we expect Abbott to handle the distribution and sale of drug candidates covered by the Abbott Alliance both inside and outside the United States. With respect to the United States, our ability to market the products that we successfully develop may be contingent on recruitment, training and deployment or outsourcing of a sales and marketing force as well as the performance of Abbott under the Abbott Alliance. We may be unable to establish marketing or sales capabilities or to maintain arrangements or enter into new arrangements with third parties to perform those activities on favorable terms. In addition, third parties may have significant control or influence over important aspects of the commercialization of our drug candidates, including market identification, marketing methods, pricing, composition of sales force and promotional activities. We may have limited control over the amount and timing of resources that a third party devotes to our products. Our business may never achieve profitability if we fail to establish or maintain a sales force and marketing, sales and distribution capabilities.

BECAUSE WE DEPEND ON THIRD PARTIES FOR THE DISCOVERY AND DEVELOPMENT OF DRUG CANDIDATES, WE MAY NOT SUCCESSFULLY ACQUIRE ADDITIONAL DRUG CANDIDATES OR DEVELOP OUR CURRENT DRUG CANDIDATES.

We do not currently intend to engage in drug discovery. Our strategy for obtaining additional drug candidates is to utilize the relationships of our management team and scientific consultants to identify drug candidates for in-licensing from companies, universities, research institutions and other organizations. We may not succeed in acquiring additional drug candidates on acceptable terms or at all.

Because we have engaged and intend to continue to engage third party contract research organizations and other third parties to help us develop our drug candidates, many important aspects of our drug development programs have been and will continue to be outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us. If the contract research organizations do not perform clinical trials in a satisfactory manner or breach their obligations to us, the development and commercialization of any drug candidate may be delayed or precluded.

BECAUSE WE MAY NOT BE ABLE TO ATTRACT AND RETAIN KEY PERSONNEL AND ADVISORS, WE MAY NOT SUCCESSFULLY DEVELOP OUR DRUG CANDIDATES OR ACHIEVE OUR OTHER BUSINESS OBJECTIVES.

We are highly dependent on our senior management and scientific staff. The loss of the services of any member of our senior management or scientific staff may significantly delay or prevent the achievement of product development and other business objectives. In order to pursue our drug development programs and marketing plans, we will need to hire additional qualified scientific and management personnel. We are currently conducting a search to fill the position of chief executive officer and it may prove difficult to find an appropriate person to fill this position. Competition for qualified individuals is intense and we face competition from numerous pharmaceutical and biotechnology companies, universities and other research institutions. If we are not able to attract and retain these individuals we may not be able to successfully commercialize our drug candidates.

HEALTH CARE REFORM MEASURES AND THIRD PARTY REIMBURSEMENT PRACTICES ARE UNCERTAIN AND MAY DELAY OR PREVENT THE COMMERCIALIZATION OF OUR DRUG CANDIDATES.

The efforts of governments and third party payors to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A number of legislative and regulatory proposals to change the health care system have been considered in recent years. In addition, an increasing emphasis on managed care in the United States has and will continue to increase pressure on drug pricing. Legislative or regulatory proposals or changes in managed care systems may be adopted that may have a negative effect on our business. The announcement and/or adoption of proposals could have an adverse effect on our ability to earn profits and financial condition. Sales of prescription drugs depend significantly on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. These third party payors frequently require that drug companies give them predetermined discounts from list prices, and they are increasingly challenging the prices for medical products and services. Present combination treatment regimens for the treatment of HIV are expensive and costs may increase as new combinations are developed. These costs have resulted in limitations in the reimbursement available from third party payors for the treatment of HIV infection, and we expect these limitations will continue in the future. Third party payors may not consider products we may bring to the market cost effective and may not reimburse the consumer sufficiently to allow us to sell our products on a profitable basis.

IF OUR DRUG CANDIDATES DO NOT ACHIEVE MARKET ACCEPTANCE, OUR BUSINESS MAY NEVER ACHIEVE PROFITABILITY.

Our success will depend on the market acceptance of any products we develop. The degree of market acceptance will depend on a number of factors, including:

- the receipt and scope of regulatory approvals,
- the establishment and demonstration in the medical community of the safety and effectiveness of our products and their potential advantages over existing treatment methods, and
- reimbursement policies of government and third party payors.



Physicians, patients, payors or the medical community in general may not accept or utilize any product that we may develop.

WE MAY NOT HAVE ADEQUATE INSURANCE PROTECTION AGAINST PRODUCT LIABILITY.

Our business exposes us to potential product liability risks that are inherent in the testing of drug candidates and the manufacturing and marketing of drug products and we may face product liability claims in the future. We currently have only limited product liability insurance. We may be unable to maintain our existing insurance and/or obtain additional insurance in the future at a reasonable cost or in sufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against us could require us to pay substantial amounts that would decrease our profitability, if any.

WE MAY INCUR SUBSTANTIAL COSTS RELATED TO OUR USE OF HAZARDOUS MATERIALS.

We use hazardous materials, chemicals, viruses and various radioactive compounds in our drug development programs. Although we believe that our handling and disposing of these materials comply with state and federal regulations, the risk of accidental contamination or injury still exists. We could be held liable for any damages or fines that result from any accidental contamination or injury and the liability could exceed our resources.

OUR CONTROLLING STOCKHOLDERS MAY MAKE DECISIONS YOU DO NOT CONSIDER TO BE IN YOUR BEST INTEREST.

As of January 31, 2002, our directors, executive officers and their affiliates, excluding Abbott and Warburg Pincus Private Equity VIII, L.P., owned approximately 11.1% of our outstanding common stock. Abbott owned approximately 10.3% of our outstanding common stock and Warburg Pincus owned approximately 30.4% of our outstanding common stock. Under the terms of the Abbott Alliance, Abbott has the right to purchase additional shares of our common stock up to a maximum aggregate percentage of 21% of our outstanding common stock and has rights to purchase shares directly from us in order to maintain its existing level of ownership. For so long as Warburg Pincus continues to own at least 5,846,222 shares of our common stock and at least 10% of our outstanding common stock, Warburg Pincus has the right to participate in any sales of equity securities by Triangle, other than sales in connection with a registered underwritten offering, a merger or similar transaction or a stock option or similar plan, in proportion to the percentage of all outstanding securities of Triangle held by Warburg Pincus at the time of the transaction. Abbott has the right to designate one person to serve as a member of our Board of Directors and Warburg Pincus has the right to designate two people to serve as members of our

Board of Directors. As a result, our controlling stockholders are able to significantly influence all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership could also delay or prevent a change in control of Triangle that may be favored by other stockholders.

THE MARKET PRICE OF OUR STOCK MAY FALL AS A RESULT OF MARKET VOLATILITY AND FUTURE DEVELOPMENTS IN OUR INDUSTRY.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors,
- announcements of the timing of regulatory submissions and/or approvals by us or our competitors,
- developments with respect to patents or proprietary rights,
- announcements of technological innovations by us or our competitors,
- announcements of new products or new contracts by us or our competitors,
- actual or anticipated variations in our operating results, including targeted cash usage, due to the level of development expenses and other factors,
- changes in financial estimates by securities analysts and whether our earnings meet or exceed analysts' estimates,
- conditions and trends in the pharmaceutical and other industries,
- new accounting standards,



- general economic, political and market conditions and other factors, and
- the occurrence of any of the risks described in these "Risk and Uncertainties."

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action law suits have often been brought against those companies. If we face litigation in the future, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

APPROXIMATELY 32,900,000 SHARES OF OUR COMMON STOCK MAY BE SOLD WITHOUT RESTRICTION AND APPROXIMATELY 37,360,000 SHARES ARE REGISTERED FOR SALE. SALES OF A LARGE NUMBER OF OUR SHARES MAY CAUSE OUR STOCK PRICE TO FALL EVEN IF OUR BUSINESS IS DOING WELL.

If our stockholders sell a substantial number of shares of our common stock in the public market, the market price of our common stock could decline. As of January 31, 2002, there were 76,828,854 shares of common stock outstanding, of which approximately 32,900,000 were immediately eligible for resale in the public market without restriction. Holders of approximately 37,360,000 shares have rights to cause us to register their shares for sale to the public and we have filed registration statements to register the sale of these shares. In addition, Abbott will have the right on or after June 30, 2002 to cause us to register for resale in the public market the 6,571,428 shares of common stock purchased at the closing of the Abbott Alliance.

Declines in our stock price might harm our ability to issue equity or secure other types of financing arrangements. The price at which we issue shares is generally based on the market price of our common stock and a decline in our

stock price would result in our needing to issue a greater number of shares to raise a given amount of funds or acquire a given amount of goods or services. For this reason, a decline in our stock price might also result in increased ownership dilution to our stockholders.

PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD DELAY OR PREVENT A CHANGE IN MANAGEMENT OR A TAKEOVER ATTEMPT THAT YOU CONSIDER TO BE IN YOUR BEST INTEREST.

We have adopted a number of provisions that could deter an acquisition of Triangle which was not approved by our Board of Directors. We have adopted a preferred stock purchase rights plan, commonly referred to as a "poison pill." The rights plan is intended to deter an attempt to acquire Triangle in a manner or on terms not approved by the Board of Directors. The rights plan will not prevent an acquisition of Triangle which is approved by the Board of Directors. Our charter authorizes the Board of Directors to determine the terms of any shares of undesignated preferred stock and issue them without stockholder approval. The issuance of preferred stock may make it more difficult for a third party to acquire, or may discourage a third party from acquiring, voting control of Triangle.

Provisions in our charter and bylaws, as well as some provisions of Delaware law could delay or prevent the removal of incumbent directors and could make more difficult a merger, tender offer or proxy contest involving Triangle, even if the events could be beneficial to our stockholders. For example, our bylaws divide the Board of Directors into three classes of directors with each class serving a three year term. These provisions could also limit the price that investors might be willing to pay for our common stock.

FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K regarding the dates on which we anticipate commencing clinical trials with, or commercializing, our drug candidates, anticipated developments in the markets for anti-HIV and anti-hepatitis B drugs, estimated development costs for our drug candidates and estimates of the date through which we believe our working capital will satisfy our capital requirements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are only predictions and reflect our current beliefs and expectations. Actual events, results and timing may differ materially. With respect to the dates on which we anticipate commencing clinical trials, we have made assumptions regarding, among other things, the successful and timely completion of preclinical tests, the approval to conduct clinical trials by the FDA or other regulatory authorities, the availability of adequate supplies of drug substance, the pace of patient enrollment and the availability of the capital resources necessary to complete



preclinical tests and conduct clinical trials. With respect to commercialization, we have made assumptions regarding, among other things, the timing of our receipt of FDA marketing approval. With respect to future developments in the markets for anti-HIV and anti-hepatitis B drugs, our assumptions include, among other things, that the number of individuals infected with HIV and hepatitis B will continue to increase, that current therapies will continue to have only limited effectiveness in controlling the viruses, and that additional drugs with improved safety or effectiveness will be developed. Our estimate for the development costs of our drug candidates through regulatory approval are based on assumptions regarding the number and size of clinical trials, the cost and time to complete clinical trials, the cost to manufacture

clinical trial materials and the anticipated cost associated with regulatory filings, among others. Our estimate of the date through which our working capital will satisfy our capital requirements is based on assumptions regarding, among other things, the progress of our drug development programs, the magnitude of these programs, the scope and results of preclinical testing and clinical trials, the cost, timing and outcome of regulatory reviews, costs under the license and/or option agreements relating to our drug candidates (including the costs of obtaining patent protection for our drug candidates), the timing and the terms of the acquisition of any additional drug candidates, the magnitude of administrative and legal expenses, the costs of establishing internal capacity and third party arrangements for sales and marketing functions, the costs of establishing third party arrangements for manufacturing, changes in interest rates and foreign currency exchange rates, and losses on our investment portfolio. Our ability to commence clinical trials on the dates anticipated, commercialization, developments in the markets for anti-HIV and anti-hepatitis B drugs, estimates for development costs and the date through which our working capital will satisfy our capital requirements are subject to numerous risks, including the risks discussed under the caption "Risk and Uncertainties" contained elsewhere in this Form 10-K. You should not place undue reliance on the dates on which we anticipate commencing clinical trials with respect to any of our drug candidates, anticipated commercialization dates, anticipated increases in the markets for anti-HIV and anti-hepatitis B drugs, our estimate for development costs or our estimate of the date through which our working capital will satisfy our capital requirements. These estimates are based on our current expectations, which may change in the future due to a large number of potential events, including unanticipated future developments.



## ITEM 2. PROPERTIES

As of January 1, 2002, we occupied an approximately 101,000 square foot administrative office and laboratory facility encompassed in two adjacent buildings in Durham, North Carolina, of which we sublease approximately 21,000 square feet to third parties. We believe our facilities will be adequate to meet our needs through September 2003 when our lease terminates.

## ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. As of the date of this Annual Report on Form 10-K, we are not a party to any legal proceedings. Emory, from which we have licensed several of our drug candidates, is a party to several opposition proceedings and two lawsuits in Australia regarding certain of the patents and patent applications related to amdoxovir. We cannot assure you that Emory will prevail in any of these proceedings and any significant adverse development with respect to Emory's claims could have a material adverse effect on us and our ability to commercialize this drug candidate. Emory has agreed with Shire Pharmaceuticals to the terms of a settlement relating to Coviracil, though the settlement has not yet been finalized. Any development adverse to our interests could have a material adverse effect on our future consolidated financial position, results of operations and cash flow. In addition, we are obligated to reimburse Emory for certain expenses related to these proceedings and these expenses could be substantial.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

a. A Special Meeting of Stockholders of Triangle Pharmaceuticals, Inc. was held on October 10, 2001. The holders of 42,432,747 of the 58,009,920 shares of Triangle's common stock outstanding on the record date were present at the Special Meeting in person or by proxy.

b. At the Special Meeting, a proposal to approve the terms of the issuance of 18,673,885 shares of common stock, par value $0.001 per share, in a two-stage private placement at a price per share of $2.65 was approved. On August 24, 2001, at the first closing of the private placement, Triangle issued 9,628,002 shares of common stock to Warburg Pincus Private Equity VIII, L.P. Upon the receipt of stockholder approval, Triangle issued an additional 18,673,885 shares of common stock in the second closing of the private placement to Warburg Pincus and additional investors. The number of votes cast for, against and to abstain on the proposal are indicated below:

| FOR | AGAINST | ABSTENTIONS |
|---|---|---|
| 42,159,558 | 169,733 | 103,456 |

At the Special Meeting, a proposal to amend Triangle's Second Restated Certificate of Incorporation was approved, increasing the number of authorized shares of capital stock to 175,000,000 shares of common stock and 10,000,000 shares of preferred stock. The number of votes cast for, against and to abstain on the proposal are indicated below:

| FOR | AGAINST | ABSTENTIONS |
|---|---|---|
| 41,808,500 | 520,428 | 103,819 |



PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

(a) Market Price of and Dividends on the Registrant's Common Equity.

Our common stock is traded on the Nasdaq National Market under the symbol "VIRS." The following table sets forth the high and low sale prices for the common stock on the Nasdaq National Market in the last two fiscal years and through March 20, 2002:

| | HIGH | LOW |
|---|---|---|
| YEAR ENDED DECEMBER 31, 2000: | | |
| 1st Quarter | $27.25 | $11.50 |
| 2nd Quarter | 15.00 | 4.88 |

| | | |
|---|---|---|
| 3rd Quarter | 11.06 | 5.00 |
| 4th Quarter | 9.44 | 4.50 |
| | | |
| YEAR ENDED DECEMBER 31, 2001: | | |
| 1st Quarter | $ 8.75 | $ 4.50 |
| 2nd Quarter | 6.45 | 3.75 |
| 3rd Quarter | 4.75 | 2.25 |
| 4th Quarter | 4.50 | 2.90 |
| | | |
| YEAR ENDED DECEMBER 31, 2002: | | |
| 1st Quarter (through March 20, 2002) | $ 5.95 | $ 3.60 |

On March 20, 2002, the last reported sale price of our common stock was $5.65 per share. As of January 31, 2002, there were approximately 500 holders of record, and approximately 4,900 beneficial holders of our common stock. We have never declared or paid any cash dividends on our capital stock. We currently do not intend to pay any cash dividends on our common stock in the foreseeable future.



## ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated statement of operations data with respect to the years ended December 31, 2001, 2000, 1999, 1998 and 1997, and the consolidated balance sheet data at December 31, 2001, 2000, 1999, 1998 and 1997, set forth below are derived from our consolidated financial statements which have been audited by PricewaterhouseCoopers LLP, independent accountants. The selected consolidated financial data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Item 7, and our consolidated financial statements and the notes thereto contained in Item 8. Historical results are not necessarily indicative of our future consolidated results.

| | YEAR ENDED DECEMBER 31, | | | |
|---|---|---|---|---|
| | 2001 | 2000 | 1999 | |
| | (IN THOUSANDS, EXCEPT PER SHARE A | | | |
| STATEMENT OF OPERATIONS DATA: | | | | |
| Revenue: | | | | |
| Collaborative revenue | $ 5,795 | $ 7,294 | $ -- | $ |
| Operating expenses: | | | | |
| License fees | 1,691 | 4,530 | 9,965 | |
| Development | 71,601 | 101,364 | 85,336 | |
| Purchased research and development (1) | 320 | 5,350 | 1,247 | |
| Selling, general and administrative | 8,456 | 12,900 | 14,638 | |
| Restructuring | 2,342 | -- | -- | |
| Total operating expenses | 84,410 | 124,144 | 111,186 | |
| Loss from operations | (78,615) | (116,850) | (111,186) | ( |
| (Loss)gain on investments, net | (924) | (334) | (62) | |
| Interest income, net | 3,613 | 7,659 | 6,627 | |

| | | | | |
|---|---|---|---|---|
| Net loss | $ (75,926) | $(109,525) | $(104,621) | $ ( |
| Basic and diluted net loss per common share (2) | $ (1.40) | $ (2.87) | $ (3.18) | $ |
| Shares used in computing basic and diluted net loss per common share (2) | 54,084 | 38,118 | 32,923 | |

| | DECEMBER 31, | | | |
|---|---|---|---|---|
| | 2001 | 2000 | 1999 | |
| | | | (IN THOUSANDS) | |
| BALANCE SHEET DATA: | | | | |
| Cash and cash equivalents | $ 64,994 | $ 14,055 | $ 58,486 | $ |
| Working capital (3) | 54,148 | 15,727 | 123,649 | |
| Investments | 43,161 | 48,876 | 99,265 | |
| Total assets | 114,165 | 71,061 | 166,497 | 1 |
| Long-term debt | 1,680 | -- | 9 | |
| Deferred revenue | 18,626 | 24,420 | 25,000 | |
| Accumulated deficit during development stage | (406,895) | (330,969) | (221,444) | (1 |
| Total stockholders' equity | 63,953 | 13,781 | 115,273 | 1 |

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(1) See note 10 of notes to consolidated financial statements for information concerning our acquisition of Avid on August 28, 1997. As a result of the acquisition, we recorded an in-process research and development charge of approximately $11.3 million in 1997, an additional charge of $1.2 million in 1999, an additional charge of $5.4 million in 2000 and an additional charge of $320,000 in 2001. The operating results of Avid have been included in our consolidated financial statements from the date of the acquisition.

(2) See note 1 of notes to consolidated financial statements for information concerning the computation of basic and diluted net loss per common share and shares used in computing net loss per common share.

(3) Working capital represents the difference between our current assets and current liabilities.



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

THIS ANNUAL REPORT ON FORM 10-K MAY CONTAIN PROJECTIONS, ESTIMATES AND OTHER FORWARD-LOOKING STATEMENTS THAT INVOLVE A NUMBER OF RISKS AND UNCERTAINTIES, INCLUDING THOSE DISCUSSED ABOVE AT "ITEM 1. BUSINESS--RISK AND UNCERTAINTIES"

AND "ITEM 1. BUSINESS--RISK AND UNCERTAINTIES--FORWARD-LOOKING STATEMENTS." WHILE THIS OUTLOOK REPRESENTS MANAGEMENT'S CURRENT JUDGMENT ON THE FUTURE DIRECTION OF THE BUSINESS, THESE RISKS AND UNCERTAINTIES COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM ANY FUTURE PERFORMANCE SUGGESTED BELOW. WE UNDERTAKE NO OBLIGATION TO RELEASE PUBLICLY THE RESULTS OF ANY REVISIONS TO THESE FORWARD-LOOKING STATEMENTS TO REFLECT EVENTS OR CIRCUMSTANCES ARISING AFTER THE DATE HEREOF.

OVERVIEW

Triangle is engaged in the development of new drug candidates primarily for serious viral diseases. Since our inception on July 12, 1995, our operating activities have related primarily to developing our drug candidates, raising working capital, negotiating license and option arrangements for our drug candidates and recruiting personnel. We have not received any revenues from the sale of products and do not believe it likely that any of our drug candidates will be commercially available before the year 2003. As of December 31, 2001, our accumulated deficit was approximately $406.9 million.

We require substantial working capital to fund the development and potential commercialization of our drug candidates. We will require significant expenditures to fund preclinical testing, clinical research studies, drug synthesis and manufacturing, license obligations, development of a sales and marketing infrastructure and ongoing administrative support before receiving regulatory approvals for our drug candidates. These approvals may be delayed or not granted at all. We have been unprofitable since our inception and expect to incur substantial losses for the next several years. Because of the nature of our business, we expect that losses will fluctuate from period to period and that fluctuations may be substantial.

You should consider the operating and financial risks associated with drug development activities when evaluating our prospects. To address these risks we must, among other things, successfully develop and commercialize our drug candidates, secure and maintain all necessary proprietary rights, respond to a rapidly changing competitive market, obtain additional financing and continue to attract, retain and motivate qualified personnel. We cannot assure you that we will be successful in addressing these risks.

Our operating expenses are difficult to predict and will depend on several factors. Development expenses, including expenses for drug synthesis and manufacturing, preclinical testing and clinical research activities, will depend on the ongoing requirements of our drug development programs, availability of capital and direction from regulatory agencies, which are difficult to predict. Management may in some cases be able to control the timing of development expenses in part by accelerating or decelerating preclinical testing and clinical trial activities, but many of these expenditures will occur irrespective of whether our drug candidates are approved when anticipated or at all. As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our consolidated operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

RESULTS OF OPERATIONS

COLLABORATIVE REVENUE

Collaborative revenue totaled $5.8 million in 2001 as compared to $7.3 million in 2000 and no revenue in 1999. Revenue in 2001 and 2000 is solely related to $31.7 million of gross non-contingent research and development expense reimbursements associated with the Abbott Alliance, which is being

amortized over the anticipated research and development arrangement period. The decrease in revenue in 2001, as compared to 2000, reflects an extension of the research and development period in which these reimbursements are to be recognized.



LICENSE FEES

License fees totaled $1.7 million in 2001, compared to $4.5 million in 2000 and $10.0 million in 1999. License fees in 2001 and 2000 related to the recognition of milestone obligations and preservation fees under our license agreements and license or option agreement initiation and/or preservation fees for several of our drug candidates. License fees in 1999 related to achievement of milestone obligations, license fees associated with the license and settlement agreements with Glaxo on the use of emtricitabine to treat hepatitis B, and license preservation fees for our drug candidate portfolio. The decrease in 2001, as compared to 2000 and 1999, is related to the timing and magnitude of milestone obligations, the magnitude of license or option preservation payments, the timing of license initiation fees, and the termination of several licensing arrangements associated with our portfolio of drug candidates. Future license fees may consist of milestone payments or annual preservation payments under existing licensing arrangements, the amount of which could be substantial and the timing of which will depend on a number of factors that we cannot predict. These factors include, among others, the success of our drug development programs and the extent to which we may in-license additional drug candidates.

DEVELOPMENT EXPENSES

Development expenses totaled $71.6 million in 2001, compared to $101.4 million in 2000 and to $85.3 million in 1999. Development expenses in 2001 were primarily for drug synthesis and manufacturing, clinical trials, employee compensation, consulting, patent related activity and preclinical testing. Development expenses in 2000 were primarily for drug synthesis and manufacturing, clinical trials, employee compensation, preclinical testing and consulting. Development expenses in 1999 were primarily for drug synthesis and manufacturing, preclinical testing, clinical trials, employee compensation and consulting expenses. The decrease in 2001 development expenses as compared to 2000 and 1999 is due to the reduced development activities for Coactinon and mozenavir dimesylate, and less development expense on Coviracil, due to decreased manufacturing and clinical costs, as we approached completion of our Phase III program. In addition, there was an overall reduction in indirect development expenses correlating with decreased Coviracil, Coactinon and mozenavir dimesylate project spending as well as our corporate restructuring that occurred in August 2001. While overall 2001 development expenses decreased from 2000, development spending on amdoxovir, clevudine, and ISS increased as these projects are evolving into later and more costly stages of development.

The termination of our license agreements for Coactinon in January 2002, mozenavir dimesylate in November 2001, and the license and collaboration agreement with Arrow in September 2001 eliminates any future license, milestone, royalty, patent and development obligations to the respective licensors in the underlying license and/or collaboration agreements. In addition, we are in the process of terminating all development activities associated with those initiatives.

Development expenses by major project for fiscal 2001 and 2000 are shown below (dollars in thousands).

| COMPOUND | INDICATION | 2001 COSTS | % | 2000 COSTS |
|---|---|---|---|---|
| Coviracil | HIV | $ 23,700 | 33 | $ 48,152 |
| Amdoxovir | HIV | 11,598 | 16 | 7,649 |
| Clevudine | Hepatitis B | 2,391 | 3 | 1,775 |
| Emtricitabine | Hepatitis B | 4,348 | 6 | 3,036 |
| ISS | Hepatitis B | 2,063 | 3 | 752 |
| Coactinon | HIV | 4,854 | 7 | 12,525 |
| Mozenavir dimesylate(1) | HIV | 353 | 1 | 2,136 |
| Other drug candidates | | 1,247 | 2 | 938 |
| Indirect (unallocated) development costs | | 21,047 | 29 | 24,401 |
| Total | | $ 71,601 | 100 | $101,364 |

(1) Excludes all purchased research and development expenses, which are solely related to mozenavir dimesylate.



We believe our 2002 development expenses may be slightly below those of 2001. Our future development expenses, however, will depend on the results and magnitude of our clinical and preclinical activities, our targeted future cash usage, availability of capital to simultaneously fund multiple drug candidate development programs and requirements imposed by regulatory agencies. Accordingly, our development expenses may fluctuate significantly from period to period. In addition, if we in-license or out-license rights to drug candidates our development expenses may fluctuate significantly from prior periods.

PURCHASED RESEARCH AND DEVELOPMENT EXPENSE

Purchased research and development expense totaled $320,000 in 2001, $5.4 million in 2000 and $1.2 million in 1999. Purchased research and development expense in 2001, 2000, and 1999 relates to the issuance of 100,000, 400,000 and 100,000 shares of our common stock, respectively, as consideration to the former Avid shareholders for milestone obligations associated with our development of mozenavir dimesylate. These in-process research and development charges are based upon the fair market value of our common stock at the date on which an obligation to the former Avid shareholders existed. The 2001 issuance of 100,000 shares satisfies all current and any future obligations for contingent development milestones for mozenavir dimesylate. However, there remains a contingency for the issuance of 250,000 shares of common stock if development milestones are achieved regarding compounds for the treatment of hepatitis B, although we are not currently developing these compounds. Issuance of any additional contingent shares would be recorded as additional purchase price and will be allocated on resolution of the underlying contingency.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses totaled $8.5 million in 2001, compared to $12.9 million in 2000 and $14.6 million in 1999. Selling, general and administrative expenses in 2001 and 2000 consisted primarily of employee compensation, third party marketing, legal, investor relations and other professional services and rent expense. Selling, general and administrative expenses in 1999 consisted primarily of third party marketing, legal, investor relations and other professional services, employee compensation and rent expense. The decrease in 2001 as compared to 2000 and 1999, is due to a reduction in 2001 sales and marketing expenses, as well as reduced employee compensation and related expenses which resulted from our August 2001 restructuring. Our selling, general and administrative expenses may fluctuate from period to period and such fluctuations may be significant. Future selling, general and administrative expenses will depend on the level of our future development and commercialization activities and the commercial availability of our products. We expect that our selling, general and administrative expenses will increase in future periods that immediately precede and follow our first product launch.

RESTRUCTURING EXPENSE

Restructuring expense totaled $2.3 million in 2001 as compared to no expense in 2000 and 1999. In August 2001, we announced and initiated a restructuring of our development activities and overall operations designed to lower our near-term monthly cash usage and to focus our financial and human resources on activities that are expected to have the highest probability of near-term regulatory approval and economic return. This focus included a significant reduction in headcount, weighting our resources towards our drug candidates in Phase III development, eliminating most resources dedicated to basic research, and reducing resources dedicated to sales, marketing and general administration.

LOSS ON INVESTMENTS, NET

Loss on investments totaled $924,000 in 2001, compared to $334,000 in 2000 and $62,000 in 1999. Realized losses on our investment portfolio represent a write-down of our strategic investment in 2001, and normal realized losses on our general investment portfolio in 2000 and 1999. Generally, we hold investments until they mature and, typically, do not incur significant realized gains or losses on our portfolio. In 2001, we recorded a $1.0 million loss on our strategic investment in Dynavax based upon the underlying estimated fair market value of the investment.



INTEREST INCOME, NET

Net interest income totaled $3.6 million in 2001, compared to $7.7 million in 2000 and $6.6 million in 1999. The significant decrease in interest income in 2001, as compared to 2000 and 1999, is due to lower short-term, low-risk interest rates and smaller average investment balances. Future interest income will depend on our future cash and investment balances and the return on these investments.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception (July 12, 1995) primarily with the net proceeds received from private placements of equity securities, which have provided aggregate net proceeds of approximately $353.1 million, and from public offerings of common stock, which have provided aggregate net

proceeds of approximately $97.7 million, as well as $31.5 million of net non-contingent research and development reimbursement proceeds from the Abbott Alliance.

At December 31, 2001, we had net working capital of $54.1 million, an increase of approximately $38.4 million over December 31, 2000. The increase in working capital is principally the result of three separate private equity financings, partially offset by use of funds for our normal operating expenses. In 2001, we raised $124.9 million of net proceeds from equity financings. Our principal sources of liquidity at December 31, 2001 were $65.0 million in cash and cash equivalents, $42.2 million in investments which are considered "available-for-sale," and $1.0 million of strategic corporate investments, reflecting a $45.2 million increase of cash, cash equivalent and investment balances over those at December 31, 2000.

As part of our drug development strategy, we outsource significant amounts of our preclinical and clinical programs and the manufacture of drug substance used in those programs. Accordingly, we have entered into contractual arrangements with selected third parties to provide these services. At December 31, 2001, we estimate the contractual commitment related to preclinical and clinical testing to be approximately $20.6 million and the contractual commitment to provide drug manufacturing to be approximately $5.0 million. These estimates may change in the future depending on the outcome of several project-related variables. Also at December 31, 2001, we have future contractual commitments to repay $3.1 million of corporate debt obligations and $3.3 million of lease obligations for our administrative office and laboratory facilities.

Our working capital requirements may fluctuate in future periods depending on many factors, including the efficiency of manufacturing processes developed on our behalf by third parties, the cost of drugs supplied by third party contractors (including Abbott), the magnitude, scope and timing of our drug development programs, the cost, timing and outcome of regulatory reviews and changes in regulatory requirements, costs under the license and/or option agreements relating to our drug candidates, including the costs of obtaining patent protection for our drug candidates, the timing and terms of business development activities related to current and new drug candidates, the rate of technological advances relevant to our operations, the timing, method and cost of the commercialization of our drug candidates, the level of required administrative and legal support, the availability of capital to support multiple drug candidate development programs and the potential expansion of facility space.

Amounts payable by us in the future under our existing license and research agreements are uncertain due to a number of factors, including the progress of our drug development programs, our ability to obtain regulatory approval to commercialize drug candidates and the commercial success of approved drugs. Our existing license and research agreements, excluding any obligations associated with Coactinon which was formally terminated in January 2002, may require future cash payments of up to $57.3 million contingent on the achievement of development milestones, up to $30.0 million on the achievement of sales milestones, and $2.2 million of future research and development payments. We are also obligated to issue 250,000 shares of common stock if development milestones are achieved regarding compounds for the treatment of hepatitis B obtained in the Avid acquisition, although we are not currently developing these compounds. Additionally, we are obligated to pay royalties of 7.5% to 22% of net sales of each licensed product incorporating drug candidates currently in our portfolio. Most of our license agreements require minimum royalty payments commencing three years after regulatory approval of the licensed compound. Depending on our success and timing in obtaining regulatory approval, aggregate annual minimum royalties and license preservation fees under our existing license agreements could range from $50,000 if only a single drug candidate is approved for one indication, to $47.0 million if all drug candidates are

approved for



all indications. In addition, we have license and collaboration agreements that allow us to obtain licenses on additional drug candidates in the future. If these collaborative arrangements identify additional drug candidates, our license obligations would increase.

We believe that our existing cash, cash equivalents and investments will be adequate to satisfy our anticipated working capital requirements through the second quarter of 2003. We are targeting a 2002 cash usage, excluding the effect of any additional financings, of approximately $61 million. However, we expect that we will be required to raise additional capital to fund our future operations through equity or debt financings or from other sources. Our future financing needs will depend on the results of clinical trials, size of drug candidate portfolio, timing of regulatory filings and approvals, commercial potential of our drug candidates and our ability to successfully commercialize our drug candidates. We may also consider modifying the timing or scope of our clinical programs or out-licensing one or more of our compounds which may impact our anticipated capital requirements. Additional funding may not be available on favorable terms from any of these sources or at all. Our ability to achieve our cash usage target is subject to several risks including unanticipated cost overruns, the need to expand the magnitude or scope of existing development programs, the need to change the number or timing of clinical trials, unanticipated regulatory requirements and other factors described under the caption "Risk and Uncertainties" elsewhere in this Form 10-K.

EQUITY FINANCINGS

In 2001, we completed three private equity financings which yielded $133.2 million in gross proceeds and significantly enhanced our liquidity and financial position as we prepare for a third quarter 2002 Coviracil NDA submission for the treatment of HIV. On March 1, 2001, we completed a private placement sale of 7.7 million shares of our common stock at $6.00 per share for net proceeds totaling approximately $43.5 million to a limited number of qualified institutional buyers and large institutional accredited investors. Abbott and QFinance, Inc., related parties of Triangle, participated in this financing. We completed the sale of 200,000 shares of convertible Series B preferred stock for $60.00 per share in a private offering to a small number of qualified institutional buyers and large institutional accredited investors on March 9, 2001. This sale yielded net proceeds of approximately $10.9 million. On May 18, 2001, our stockholders approved the issuance of the Series B preferred stock, which triggered the conversion of each preferred share into ten shares of our common stock. As part of this transaction, we filed a registration statement covering the resale of these common shares, which the Securities and Exchange Commission declared effective on July 11, 2001.

On August 24, 2001, we entered into a purchase agreement with Warburg Pincus for the sale of 28,301,887 shares of common stock in a two-stage private placement at a purchase price of $2.65 per share. On the same day, we issued 9,628,002 shares of common stock in the first closing of the private placement for net proceeds totaling approximately $24.0 million. On October 10, 2001, the second closing occurred, resulting in net proceeds totaling approximately $46.6 million from the sale of an additional 13,756,885 shares of our common stock to Warburg Pincus and an additional 4,917,000 shares of common stock to other investors. In the purchase agreement with Warburg Pincus, we agreed to register the shares of common stock sold in both closings, agreed to cause two individuals nominated by Warburg Pincus to be appointed to the Board of Directors, and granted Warburg Pincus rights to participate in certain future

sales of common stock. Accordingly, we filed a registration statement with the Securities and Exchange Commission on October 18, 2001 covering the resale of 28,301,887 shares of common stock by Warburg Pincus and the other investors in the October private placement; two additional directors affiliated with Warburg Pincus were elected to the Board of Directors; and Warburg Pincus has the right to participate proportionally in future equity financings, as long as Warburg Pincus owns approximately 5,846,000 shares of our outstanding common stock. The Securities and Exchange Commission declared the registration statement effective on February 13, 2002.

TERMINATED AGREEMENTS

In conjunction with our restructuring and cash conservation initiatives, we performed a critical evaluation of our development activities and projects, which resulted in the termination of several license and collaboration agreements. The elimination of these development projects was designed to eliminate financial and human resources dedicated to basic research and to focus our available resources on development initiatives we believe to have the highest probability for success and most immediate economic return. In September 2001, we terminated



our licensing and collaborative agreement with Arrow. This collaboration had been established to identify and develop novel antiviral agents for the treatment of hepatitis C and required us to fund the screening program and to pay development milestones and royalty payments on sales of products which resulted from this collaboration. In November 2001, we terminated our licensing agreement with The DuPont Pharmaceuticals Company for worldwide rights to mozenavir dimesylate for use in the HIV field. Termination of this license eliminated any future commitments to pay development milestones, patent and royalty payments for mozenavir dimesylate. In January 2002, we terminated our licensing agreement with Mitsubishi for worldwide rights, with the exception of Japan, to Coactinon for use in the HIV field. Termination of this license eliminated any future commitments to pay development milestones and royalty payments for Coactinon. We are in the process of terminating, or have terminated, all development activities associated with these initiatives.

Additionally, in October 2001, we terminated a $100.0 million Firm Underwritten Equity Facility that provided us the ability to sell our common stock in the public market. We terminated this arrangement because of the added liquidity provided by the financing led by Warburg Pincus.

LITIGATION AND OTHER CONTINGENCIES

As discussed in note 14 of the Notes to Consolidated Financial Statements, we are indirectly involved in several patent opposition and adversarial proceedings and two lawsuits filed in Australia regarding the patent rights related to our licensed drug candidate, amdoxovir. Although we are not a named party in any of these proceedings, we are obligated to reimburse our licensors for legal expenses associated with these proceedings. In one of these patent opposition proceedings, on November 8, 2000, the Australian Patent Office held that several patent claims of Emory directed to amdoxovir are not patentable over an earlier Shire Pharmaceuticals patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory, the University of Georgia or Triangle is unsuccessful in the appeal, then we will not be able to sell amdoxovir in Australia without a license from Shire Pharmaceuticals, which may not be available on reasonable terms or at all. We cannot predict the outcome of this or any of the other proceedings. We believe that an adverse judgment rendered against us would not result in a material

financial obligation, nor would we have to recognize an impairment under Statement of Financial Accounting Standards, SFAS, No. 121 "ACCOUNTING FOR IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF" (as amended by SFAS No. 144, "ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS) as no amounts have been capitalized related to this drug candidate. However, any development in these proceedings adverse to our interests, including any adverse development related to the patent rights licensed to us for this drug candidate or our related rights or obligations, could have a material adverse effect on our future operations.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles, require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discuss financial events, policies, and issues with members of our audit committee and our independent accountants. We routinely evaluate our estimates and policies regarding clinical trial, preclinical and manufacturing liabilities; patent related liabilities; license milestone obligations; revenue recognition; inventory; intangible assets and deferred tax assets.

We generally enter into contractual agreements with third-party vendors to provide clinical, preclinical and manufacturing services in the ordinary course of business. Many of these contracts are subject to milestone based invoicing and the contract could extend over several years. We record liabilities under these contractual commitments when we determine an obligation has been incurred, regardless of the timing of the invoice. Patent related and license milestone liabilities are recorded based upon various assumptions or events that we believe are the most reasonable to each individual circumstance, as well as based upon historical experience. License milestone liabilities and the related expense are recorded when the milestone criterion achievement or license preservation payment is probable. We have not recognized any assets for inventory, intangible items or deferred taxes as we have yet to receive regulatory approval for any of our drug candidates. Any potential asset that could be recorded in regards to any of these items is fully reserved. We currently recognize revenue based upon the amortization of non-contingent reimbursed research and development payments that have been received in accordance with terms of the



Abbott Alliance. The amortization period in which we recognize this revenue is based upon the estimated time period to submit all drug candidates under the Abbott Alliance for regulatory approval. This amortization period is periodically evaluated and adjusted.

In all cases, actual results may differ from our estimates under different assumptions or conditions.

SUBSEQUENT EVENT

In January 2002, our Chief Executive Officer and Chairman of the Board, Dr. David W. Barry, died unexpectedly. The Board of Directors is currently conducting a search for a qualified replacement. Additionally, we have filed a claim under a keyman insurance policy and expect a $10.0 million settlement in the first quarter of 2002.

RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board, FASB, issued SFAS No. 141, "BUSINESS COMBINATIONS" and SFAS No. 142, "GOODWILL AND OTHER INTANGIBLE ASSETS." SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS No. 142 changes the accounting for goodwill and indefinite lived intangible assets from an amortization method to an impairment-only approach.

In August 2001, the FASB issued SFAS No. 143, "ACCOUNTING FOR ASSET RETIREMENT OBLIGATIONS." The objectives of SFAS No. 143 are to establish accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. In October 2001, the FASB issued SFAS No. 144, "ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS." This statement supersedes SFAS No. 121, "ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS AND FOR LONG-LIVED ASSETS TO BE DISPOSED OF" and Accounting Principles Board Opinion No. 30, "REPORTING THE RESULTS OF OPERATIONS - REPORTING THE EFFECTS OF DISPOSAL OF A SEGMENT OF BUSINESS, AND EXTRAORDINARY, UNUSUAL AND INFREQUENTLY OCCURRING EVENTS AND TRANSACTIONS."

We adopted SFAS No. 142 and 144 as of January 1, 2002, and intend to adopt SFAS No. 143 as of January 1, 2003, as required. Adoption of SFAS Nos. 141, 142, 143 and 144 are not expected to have a significant impact on our consolidated financial position, results of operations or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Triangle is exposed to various market risks, including changes in foreign currency exchange rates, investment market value and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange and interest rates. We may enter into forward foreign currency contracts or purchase investments in foreign currencies to hedge foreign currency commitments. We have, however, established policies and procedures for market risk assessment and the approval, reporting and monitoring of derivative financial instrument activities. The following discusses our exposure to risks related to changes in interest rates, foreign currency exchange rates and investment market value.

INTEREST RATE SENSITIVITY

Triangle is subject to interest rate risk on its investment portfolio. We maintain an investment portfolio consisting primarily of high quality money market instruments, and government and corporate bonds. Our portfolio has a current average maturity of less than 12 months. We attempt to mitigate default risk by investing in high credit quality securities and by monitoring the credit rating of investment issuers. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity and we have implemented guidelines limiting the duration of investments. These available-for-sale securities are subject to interest rate risk and will decrease in value if market interest rates increase. If market rates were to increase by 10 percent from levels at December 31, 2001, we expect that the fair value of our investment portfolio would decline by an immaterial aggregate amount primarily due to the relatively short maturity of the portfolio. At December 31, 2001, our portfolio consisted of approximately $21.3 million of investments maturing within one year and approximately $20.9 million of investments maturing after one year but within 30 months. Additionally, we

generally have the ability to hold our fixed income investments to maturity and therefore do not expect that our consolidated operating results, financial position or cash flows will be affected by a significant amount due to a sudden change in interest rates.

FOREIGN CURRENCY EXCHANGE RISK

The majority of our transactions occur in U.S. dollars and we do not have subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We have, however, established policies and procedures for market risk assessment, including a foreign currency-hedging program. The goal of our hedging program is to establish fixed exchange rates on firm foreign currency cash outflows and to minimize the impact to Triangle of foreign currency fluctuations. These policies specifically provide for the hedging of firm commitments and prohibit the holding of derivative instruments for speculative or trading purposes. At December 31, 2001, we had no forward foreign currency contracts, but had investments in foreign currencies totaling approximately $250,000 used to hedge foreign currency commitments. The purchase and the holding of foreign currencies are governed by established corporate policies and procedures and are entered into when management determines this methodology to be in our best interests. These investments are subject to both foreign currency risk and interest rate risk. The hypothetical loss associated with a 10 percent devaluation of these foreign currencies would not materially affect our consolidated operating results, financial position or cash flow.

STRATEGIC INVESTMENT RISK

In addition to our normal investment portfolio, we have a strategic investment in Dynavax valued at $1.0 million. This investment represents unregistered preferred stock and is subject to higher investment risk than our normal investment portfolio due to the lack of an active resale market for the investment. In 2001, we recorded a $1.0 million loss based upon the underlying estimated fair market value of our Dynavax investment.



## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders
of Triangle Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of cash flows and of stockholders' equity present fairly, in all material respects, the financial position of Triangle Pharmaceuticals, Inc. and its subsidiary, a development stage company, (the "Company") at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 and the period from inception (July 12, 1995) through December 31, 2001, 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 our opinion.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina
February 8, 2002



TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

| | DECEMBER 31, | |
|---|---|---|
| ASSETS | 2001 | 2 |
| Current assets: | | |
| Cash and cash equivalents | $ 64,994 | $ 1 |
| Investments | 21,280 | 3 |
| Interest receivable | 798 | |
| Receivable from collaborative partner | 480 | |
| Prepaid expenses | 641 | |
| Total current assets | 88,193 | 5 |

| | | |
|---|---|---|
| Property, plant and equipment, net | 4,091 | |
| Investments | 21,881 | |
| Total assets | $ 114,165 | $ 7 |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|---|---|---|
| Current liabilities: | | |
| Accounts payable | $ 11,884 | $ |
| Payable to collaborative partner | 2,645 | |
| Debt-current | 1,454 | |
| Accrued expenses | 13,923 | 1 |
| Deferred revenue | 4,139 | |
| Total current liabilities | 34,045 | 3 |
| Debt-noncurrent | 1,680 | |
| Deferred revenue | 14,487 | 1 |
| Total liabilities | 50,212 | 5 |
| Commitments and contingencies (See notes 1, 3, 5, 8, 10, 14 and 16) | -- | |
| Stockholders' equity: | | |
| Convertible Preferred Stock, $0.001 par value; 10,000 shares authorized; 0 shares issued and outstanding | -- | |
| Common Stock, $0.001 par value; 175,000 shares authorized; 76,829 and 38,529 shares issued and outstanding, respectively | 77 | |
| Additional paid-in capital | 470,478 | 34 |
| Accumulated deficit during development stage | (406,895) | (33 |
| Accumulated other comprehensive income | 293 | |
| Total stockholders' equity | 63,953 | 1 |
| Total liabilities and stockholders' equity | $ 114,165 | $ 7 |

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



TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

| | YEAR ENDED DECEMBER 31, | | |
|---|---|---|---|
| 2001 | 2000 | 1999 | D |

| | | | |
|---|---|---|---|
| Revenue: | | | |
| Collaborative revenue | $ 5,795 | $ 7,294 | $ -- |
| Operating expenses: | | | |
| License fees | 1,691 | 4,530 | 9,965 |
| Development | 71,601 | 101,364 | 85,336 |
| Purchased research and development | 320 | 5,350 | 1,247 |
| Selling, general and administrative | 8,456 | 12,900 | 14,638 |
| Restructuring | 2,342 | -- | -- |
| Total operating expenses | 84,410 | 124,144 | 111,186 |
| Loss from operations | (78,615) | (116,850) | (111,186) |
| Loss on investments, net | (924) | (334) | (62) |
| Interest income, net | 3,613 | 7,659 | 6,627 |
| Net loss | $ (75,926) | $ (109,525) | $ (104,621) |
| Basic and diluted net loss per common share | $ (1.40) | $ (2.87) | $ (3.18) |
| Shares used in computing basic and diluted net loss per common share | 54,084 | 38,118 | 32,923 |

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



TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

| | YEAR ENDED DECEMBER 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 19 |
| Cash flows from operating activities: | | | |
| Net loss | $ (75,926) | $ (109,525) | $ (1 |
| Adjustments to reconcile net loss to net cash used by operating activities: | | | |
| Depreciation and amortization | 1,917 | 1,804 | |
| Loss(gain) from disposal of property, plant and equipment | 223 | 4 | |
| Loss on investments | 924 | 334 | |
| Purchased research and development | 320 | 5,350 | |
| Stock-based compensation | 183 | 348 | |
| Change in assets and liabilities: | | | |
| Receivables | 216 | 969 | |

| | | | |
|---|---|---|---|
| Prepaid expenses | (98) | 12 | |
| Accounts payable | (1,056) | 4,090 | |
| Accrued expenses | (3,345) | 2,681 | |
| Deferred revenue | (5,794) | (580) | |
| Net cash used by operating activities | (82,436) | (94,513) | ( |
| Cash flows from investing activities: | | | |
| Sale of restricted deposits | -- | 27 | |
| Purchase of investments | (35,762) | (90,223) | (1 |
| Proceeds from sale and maturity of investments | 40,685 | 140,574 | |
| Proceeds from sale of property, plant and equipment | 322 | 40 | |
| Purchase of property, plant and equipment | (460) | (2,240) | |
| Acquisition of Avid Corporation, net of cash acquired | -- | -- | |
| Net cash provided (used) by investing activities | 4,785 | 48,178 | ( |
| Cash flows from financing activities: | | | |
| Sale of stock, net of related issuance costs | 125,106 | 1,609 | 1 |
| Sale of options under salary investment option grant program | 68 | 52 | |
| Proceeds from stock options/warrants exercised | 289 | 378 | |
| Proceeds from notes payable | 3,419 | -- | |
| Equipment financing | -- | -- | |
| Principal payments on capital lease obligations and notes payable | (292) | (135) | |
| Net cash provided by financing activities | 128,590 | 1,904 | 1 |
| Net increase (decrease) in cash and cash equivalents | 50,939 | (44,431) | ( |
| Cash and cash equivalents at beginning of year | 14,055 | 58,486 | |
| Cash and cash equivalents at end of year | $ 64,994 | $ 14,055 | $ |

Supplemental disclosure of noncash investing and financing activities:

Cash payments for interest expense were $53, $5 and $33 in 2001, 2000 and 1999, respectively.

In November 2000, the Company granted a purchase right to acquire 300 shares of Common Stock at $13.00 per share.

In April 1999, March 2000 and September 2001, the Company issued 100 shares, 400 shares and 100 shares, respectively, of Common Stock valued at $1,247, $5,350 and $320, respectively, in conjunction with the Avid Corporation acquisition (see note 10).

In 1999, 6 shares of Common Stock were issued to an officer of the Company as compensation.

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

TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS)

| | CONVERTIBLE PREFERRED STOCK | | | COM |
|---|---|---|---|---|
| | SHARES | AMOUNT | WARRANTS | SHARES |
| Initial sale of stock ..... | 933 | $ 1 | $ -- | 1,1 |
| Additional sale of stock ..... | 4,249 | 4 | -- | 1,4 |
| Stock-based compensation ..... | -- | -- | -- | |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | -- | -- | |
| Balance, December 31, 1995 ..... | 5,182 | 5 | -- | 2,6 |
| Sale of stock ..... | 3,756 | 4 | -- | 4,9 |
| Stock-based compensation ..... | -- | -- | 152 | 7 |
| Stock options exercised ..... | -- | -- | -- | 3 |
| Conversion of Preferred to Common Stock ..... | (8,938) | (9) | -- | 8,9 |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | -- | -- | |
| Balance, December 31, 1996 ..... | -- | -- | 152 | 17,5 |
| Sale of stock ..... | -- | -- | -- | 2,0 |
| Acquisition of Avid Corp. ..... | -- | -- | -- | 4 |
| Sale of stock options ..... | -- | -- | -- | |
| Stock-based compensation ..... | -- | -- | (38) | |
| Stock options exercised ..... | -- | -- | -- | |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | -- | -- | |
| Balance, December 31, 1997 ..... | -- | -- | 114 | 19,9 |
| Sale of stock ..... | 170 | -- | -- | 8,8 |
| Sale of stock options ..... | -- | -- | -- | |
| Stock-based compensation ..... | -- | -- | -- | |
| Stock options exercised ..... | -- | -- | -- | |
| Comprehensive loss: | | | | |
| Change in unrealized gains/(losses) on investments .. | -- | -- | -- | |
| Net loss ..... | -- | -- | -- | |
| Balance, December 31, 1998 ..... | 170 | -- | 114 | 28,8 |
| Sale of stock ..... | -- | -- | -- | 6,6 |
| Sale of stock options ..... | -- | -- | -- | |
| Stock-based compensation ..... | -- | -- | -- | |
| Stock options/warrants exercised ... | -- | -- | (114) | 2 |
| Conversion of Preferred to Common Stock ..... | (170) | -- | -- | 1,7 |
| Purchased in-process research and development costs ..... | -- | -- | -- | 1 |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss ..... | -- | -- | -- | |
| Change in unrealized gains/(losses) on investments .. | -- | -- | -- | |
| Net loss ..... | -- | -- | -- | |

| | | | | |
|---|---|---|---|---|
| Balance, December 31, 1999 ..... | -- | $ -- | $ -- | 37,5 |

| | ADDITIONAL PAID-IN CAPITAL | ACCUMULATED DEFICIT | COMPREHENSIVE INCOME (LOSS) | ACCUMULATE OTHER COMPREHENSI INCOME/(LOS |
|---|---|---|---|---|
| Initial sale of stock ..... | $ 710 | $ -- | $ | $ |
| Additional sale of stock ..... | 3,137 | -- | | |
| Stock-based compensation ..... | 12 | -- | | |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | (967) | (967) | |
| Balance, December 31, 1995 ..... | 3,859 | (967) | (967) | |
| Sale of stock ..... | 59,506 | -- | | |
| Stock-based compensation ..... | 1,127 | -- | | |
| Stock options exercised ..... | 57 | -- | | |
| Conversion of Preferred to Common Stock ..... | -- | -- | | |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | (10,917) | (10,917) | |
| Balance, December 31, 1996 ..... | 64,549 | (11,884) | (10,917) | |
| Sale of stock ..... | 29,521 | -- | | |
| Acquisition of Avid Corp. ..... | 8,117 | -- | | |
| Sale of stock options ..... | 70 | -- | | |
| Stock-based compensation ..... | -- | -- | | |
| Stock options exercised ..... | 3 | -- | | |
| Comprehensive loss: | | | | |
| Net loss ..... | -- | (37,668) | (37,668) | |
| Balance, December 31, 1997 ..... | 102,260 | (49,552) | (37,668) | |
| Sale of stock ..... | 116,325 | -- | | |
| Sale of stock options ..... | 97 | -- | | |
| Stock-based compensation ..... | -- | -- | | |
| Stock options exercised ..... | 1 | -- | | |
| Comprehensive loss: | | | | |
| Change in unrealized gains/(losses) on investments .. | -- | -- | 18 | |
| Net loss ..... | -- | (67,271) | (67,271) | |
| Balance, December 31, 1998 ..... | 218,683 | (116,823) | (67,253) | |
| Sale of stock ..... | 116,211 | -- | | |
| Sale of stock options ..... | 95 | -- | | |
| Stock-based compensation ..... | 101 | -- | | |
| Stock options/warrants exercised ... | 479 | -- | | |
| Conversion of Preferred to Common Stock ..... | (2) | -- | | |
| Purchased in-process research and development costs ..... | 1,247 | -- | | |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss ..... | -- | -- | (21) | ( |
| Change in unrealized gains/(losses) on investments .. | -- | -- | (132) | (1 |
| Net loss ..... | -- | (104,621) | (104,621) | |
| Balance, December 31, 1999 ..... | $ 336,814 | $ (221,444) | $ (104,774) | $ (1 |

(CONTINUED)

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



TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS)

| | CONVERTIBLE PREFERRED STOCK | | | COM |
|---|---|---|---|---|
| | SHARES | AMOUNT | WARRANTS | SHARES |
| (CONTINUED) | | | | |
| Sale of stock | -- | $ -- | $ -- | 3 |
| Sale of stock options | -- | -- | -- | |
| Stock-based compensation | -- | -- | -- | |
| Stock options/warrants exercised | -- | -- | -- | 2 |
| Purchased in-process research and development costs | -- | -- | -- | 4 |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss | -- | -- | -- | |
| Change in unrealized gains/(losses) on investments | -- | -- | -- | |
| Net loss | -- | -- | -- | |
| Balance, December 31, 2000 | -- | -- | -- | 38,5 |
| Sale of stock | 200 | -- | -- | 36,0 |
| Sale of stock options | -- | -- | -- | |
| Stock-based compensation | -- | -- | -- | |
| Stock options/warrants exercised | -- | -- | -- | 1 |
| Purchased in-process research and development costs | -- | -- | -- | 1 |
| Conversion of Preferred to Common Stock | (200) | -- | -- | 2,0 |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss | -- | -- | -- | |
| Change in unrealized gains/(losses) on investments | -- | -- | -- | |
| Net loss | -- | -- | -- | |
| Balance, December 31, 2001 | -- | $ -- | $ -- | 76,8 |

| | ADDITIONAL PAID-IN CAPITAL | ACCUMULATED DEFICIT | COMPREHENSIVE INCOME (LOSS) | ACCUMULATE OTHER COMPREHENSI INCOME/(LOS |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Sale of stock | $ 1,608 | $ -- | $ | $ |
| Sale of stock options | 52 | -- | | |
| Stock-based compensation | 348 | -- | | |
| Stock options/warrants exercised | 378 | -- | | |
| Purchased in-process research and development costs | 5,350 | -- | | |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss | -- | -- | 133 | 1 |
| Change in unrealized gains/(losses) on investments | -- | -- | 163 | 1 |
| Net loss | -- | (109,525) | (109,525) | |
| Balance, December 31, 2000 | 344,550 | (330,969) | (109,229) | 1 |
| Sale of stock | 125,070 | -- | | |
| Sale of stock options | 68 | -- | | |
| Stock-based compensation | 183 | -- | | |
| Stock options/warrants exercised | 289 | -- | | |
| Purchased in-process research and development costs | 320 | -- | | |
| Conversion of Preferred to Common Stock | (2) | -- | | |
| Comprehensive loss: | | | | |
| Reclassification adjustment for gains/(losses) in net loss | -- | -- | (57) | ( |
| Change in unrealized gains/(losses) on investments | -- | -- | 189 | 1 |
| Net loss | -- | (75,926) | (75,926) | |
| Balance, December 31, 2001 | $ 470,478 | $ (406,895) | $ (75,794) | $ 2 |

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



TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND PRINCIPLES OF CONSOLIDATION

Triangle Pharmaceuticals, Inc. and its wholly-owned subsidiary (the "Company" or "Triangle"), a development stage company, was formed July 12, 1995, as a Delaware corporation. The Company is engaged in the development of new drug candidates primarily in the antiviral area and has not yet generated revenues from operations. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Triangle is a development stage company and has incurred losses and negative cash flows from operations since inception. The Company has sufficient liquidity to continue its planned operations through the second quarter of 2003, but expects that additional capital will be required. Continuation of its

operations beyond that date will require the Company to raise additional capital through equity or debt financings or from other sources.

CASH AND CASH EQUIVALENTS

The Company considers all short-term deposits with an initial maturity at date of purchase of three months or less to be cash equivalents. The carrying amount of cash and cash equivalents approximates fair value.

INVESTMENTS

Investments consist primarily of United States and municipal government agency obligations, corporate bonds, notes and commercial paper, preferred stock and other fixed or variable income investments. The Company invests in high-credit quality investments in accordance with its investment policy which minimizes the possibility of loss. Investments with original maturities at date of purchase beyond three months and which mature at or less than twelve months from the balance sheet date are classified as current. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term. Investments are considered to be available-for-sale and are carried at fair value with unrealized gains and losses recognized in comprehensive income/(loss). Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis.

The Company has equity investments in non-public entities for which fair values are not readily determinable. For those investments in which the Company does not have significant influence and owns less than 20% of the entity, the investments are carried at cost and are subject to a write-down for impairment whenever events or changes in circumstance indicate that the carrying value may not be recoverable. Investments for which the Company has the ability to exercise significant influence are accounted for using the equity method.

PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives as follows: laboratory equipment - 5 years; office equipment - 4 to 7 years; and leasehold improvements - the shorter of 7 years or lease-term.

REVENUE RECOGNITION

Revenue for any products that are developed will be recognized when such products are shipped. Collaborative revenue is related to non-contingent research and development reimbursement received under the Company's strategic alliance and is being recognized over the anticipated performance of research and development in accordance with the Securities and Exchange Commission Staff Accounting Bulletin No. 101, "REVENUE RECOGNITION IN FINANCIAL STATEMENTS."





1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

LICENSE FEES

License initiation and preservation fees are evaluated as to whether the

underlying drug candidate has an alternative use, and if none, are recorded as an expense. License milestone criteria are continuously evaluated and when criterion achievement is probable, the Company records expense, or will capitalize such amounts if commercial approval by a regulatory agency is obtained for the licensed compound or if the compound has an alternate future use. License preservation fees are recorded when payment is probable and the Company records expense ratably over the period for which the payment pertains.

DEVELOPMENT EXPENSE

Development expense includes all direct and indirect development costs related to the development of the Company's portfolio of drug candidates. Direct costs include services performed by outside consultants, preclinical and toxicology testing, drug synthesis and manufacturing, patent related activity, salaries for development personnel and costs incurred in conducting clinical trials. These costs have been charged to operating expense as incurred. Costs associated with obtaining and maintaining patents on the Company's drug candidates are evaluated based on the stage of development and whether the underlying drug candidate has an alternative use. If a drug candidate has not been approved for commercial sale by a regulatory agency and/or does not have an alternative use, patent related costs have been recorded as an expense. Once a drug candidate has received commercial approval, patent related costs will be capitalized and amortized over the expected life of the product.

ACCRUED EXPENSES

The carrying value of accrued expenses approximates fair value because of their short-term maturity.

DEBT

The carrying value of the Company's notes payable approximates their fair value.

INCOME TAXES

Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactment of changes in tax law or rates. If it is "more likely than not" that some portion or all of a deferred tax asset will not be realized, a valuation allowance is recorded.

NET LOSS PER COMMON SHARE

Basic net loss per common share is computed using the weighted average number of shares of Common Stock outstanding during the period. Diluted net loss per common share is computed using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. Potential common shares consist of stock options, warrants and convertible preferred stock using the treasury stock method and are excluded if their effect is antidilutive. At December 31, 2001, 2000 and 1999 had such potential common shares not been antidilutive, their effect would be to increase the shares used in computing diluted net loss per common share to 54,817, 38,793 and 34,459, respectively.

TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

COMPREHENSIVE INCOME (LOSS)

The Company calculates and discloses comprehensive income in accordance with Statement of Financial Accounting Standards ("SFAS") No. 130, "REPORTING COMPREHENSIVE INCOME." The Company discloses comprehensive income (loss) as a component in its consolidated statements of stockholders' equity.

USE OF ESTIMATES

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

STOCK-BASED COMPENSATION

The Company records stock-based compensation in accordance with SFAS No. 123, "ACCOUNTING FOR STOCK-BASED COMPENSATION." As provided by SFAS 123, the Company has elected to continue to account for its stock-based compensation programs according to the provisions of Accounting Principles Board Opinion No. 25, "ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES" ("APB 25"). Accordingly, compensation expense has been recognized to the extent of employee or director services rendered based on the intrinsic value of compensatory options or shares granted under the plans. The Company has adopted the disclosure provisions required by SFAS 123.

In March 2000, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 44, "ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION-AN INTERPRETATION OF APB 25." This interpretation clarifies the definition of employee for purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequence of various modifications to the terms of a previously fixed stock option or award, and the accounting for an exchange of stock compensation awards in a business combination.

DERIVATIVE FINANCIAL INSTRUMENTS

The Company records its derivative financial instruments in accordance with SFAS No. 133, "ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES" as deferred and amended by SFAS 137 and SFAS 138. SFAS 133, 137 and 138 establish accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities, and require the Company to recognize all derivatives as either assets or liabilities on the balance sheet and measure them at fair value. Gains and loses resulting from changes in fair value would be accounted for based on the intended use of the derivative and whether it is designated and qualifies for hedge accounting.

Derivative financial instrument contracts are entered into and utilized by the Company to manage foreign exchange risk by hedging certain transactions, or firm commitments, which are denominated in a foreign currency. The Company has established a control environment which includes policies and procedures for risk assessment and the approval, reporting and monitoring of derivative

financial instrument activities. The Company's derivative activities are subject to the management direction and control of the Risk Management Committee (the "RMC"). The RMC is composed of the Chief Financial Officer and the Treasurer.

To qualify for hedge accounting, the contracts must meet defined correlation and effectiveness criteria, be designated as hedges and result in cash flows and financial statement effects which substantially offset those of the position being hedged. The Company formally documents all relationships between hedging instruments and hedge





1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

items, as well as its risk-management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives that are designated as fair-value hedges to specific assets or liabilities or to specific firm commitments or forecasted transactions. The Company also formally assesses, both at the hedge's inception and on an ongoing basis, whether the derivatives used in hedging transactions are highly effective in offsetting changes in fair values of hedged items. The Company records these foreign exchange contracts at fair value in its consolidated balance sheet and the related gains or losses on these contracts as an offset to the hedged item. At December 31, 2001, Triangle had no foreign currency forward contracts but did have approximately $250 of investments in foreign currencies to hedge firm foreign currency commitments. For the years ended December 31, 2001, 2000 and 1999, the Company realized net gains or (losses) on foreign currency transactions of approximately $27, $46 and ($145), respectively.

RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform with the current year presentation.

OTHER RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued SFAS No. 141, "BUSINESS COMBINATIONS" and SFAS No. 142, "GOODWILL AND OTHER INTANGIBLE ASSETS." SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS No. 142 changes the accounting for goodwill and indefinite lived intangible assets from an amortization method to an impairment-only approach. In August 2001, the FASB issued SFAS No. 143, "ACCOUNTING FOR ASSET RETIREMENT OBLIGATIONS." The objectives of SFAS No. 143 are to establish accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. In October 2001, the FASB issued SFAS No. 144, "ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG-LIVED ASSETS." This statement supersedes SFAS No. 121, "ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS AND FOR LONG-LIVED ASSETS TO BE DISPOSED OF" and Accounting Principles Board Opinion No. 30, "REPORTING THE RESULTS OF OPERATIONS - REPORTING THE EFFECTS OF DISPOSAL OF A SEGMENT OF BUSINESS, AND EXTRAORDINARY, UNUSUAL AND INFREQUENTLY OCCURRING EVENTS AND TRANSACTIONS."

The Company will adopt SFAS No. 142 and 144 as of January 1, 2002, and intends to adopt SFAS No. 143 as of January 1, 2003, as required. Adoption of

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

SFAS Nos. 141, 142, 143 and 144 are not expected to have a significant impact on the Company's consolidated financial position, results of operations or cash flows.

2. INVESTMENTS

A summary of the fair market value of investments securities by classification is as follows:

| | DECEMBER 31, | |
|---|---|---|
| | 2001 | 2000 |
| United States Government obligations | $ 6,222 | $ 10,684 |
| Corporate bonds, notes and commercial paper | 30,573 | 29,934 |
| Preferred stock | 1,000 | 2,000 |
| Other | 5,366 | 6,258 |
| Total | $ 43,161 | $ 48,876 |

The Company owns 3,300 shares of TherapyEdge, Inc. (previously known as Intelligent Therapeutic Solutions, Inc., "TherapyEdge") Series A Preferred Stock and is accounting for its investment using the equity method. At December 31, 2001 and 2000, the carrying value of this investment was $0 and the Company has no obligation to fund future TherapyEdge operations.





2. INVESTMENTS (CONTINUED)

Maturities of debt securities at fair market value are as follows:

| | DECEMBER 31, | |
|---|---|---|
| | 2001 | 2000 |
| Mature in one year or less | $ 21,280 | $ 39,472 |
| Mature after one year through five years | 20,881 | 7,404 |
| Total | $ 42,161 | $ 46,876 |

Gross realized and unrealized holding gains and losses for the years ended December 31, 2001, 2000 and 1999 were not significant, with the exception of a $1,000 realized loss on our strategic investment in Dynavax Technologies

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

Corporation ("Dynavax") in 2001.

3. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consists of the following:

| | DECEMBER 31, | |
|---|---|---|
| | 2001 | 2000 |
| Laboratory equipment | $ 5,678 | $ 5,791 |
| Office equipment | 3,484 | 3,253 |
| Leasehold improvements | 481 | 465 |
| Construction-in-progress (office and laboratory equipment) | -- | 826 |
| | 9,643 | 10,335 |
| Accumulated depreciation | (5,552) | (4,242) |
| Property, plant and equipment, net | $ 4,091 | $ 6,093 |

The Company leases office and laboratory facilities and office equipment under various operating leases. Rent expense totaled $2,138, $2,233 and $1,823 for 2001, 2000 and 1999, respectively.

Future minimum lease payments under operating leases at December 31, 2001 are as follows:

| YEAR | AMOUNT |
|---|---|
| 2002 | $ 1,904 |
| 2003 | 1,427 |
| Total | $ 3,331 |

The Company has subleased office and laboratory facilities that it currently leases to non-affiliated third parties and expects its future minimum lease payments to be decreased by $384 and $293 in 2002 and 2003, respectively.





4. ACCRUED EXPENSES

Accrued expenses consist of the following:

| | DECEMBER 31, | |
|---|---|---|
| | 2001 | 2000 |
| Clinical studies | $ 7,704 | $ 13,233 |
| Professional fees | 2,755 | 1,056 |
| Drug substance | 1,120 | 1,088 |
| Compensation and benefits | 895 | 664 |
| Restructuring | 544 | -- |
| Duties and taxes | 145 | 95 |
| Other | 760 | 1,132 |
| Total | $ 13,923 | $ 17,268 |

In August 2001, Triangle initiated a restructuring of its development activities and overall operations to lower monthly cash usage and to focus financial and human resources on activities that are expected to have the highest probability of near-term regulatory approval and economic return. This focus included weighting corporate resources towards drug candidates in Phase III development, eliminating most resources dedicated to basic research, and reducing resources dedicated to sales, marketing and general administration. Accordingly, the Company recorded a restructuring charge of $2,342 of which approximately $1,650 was for severance and other termination benefits related to an approximate 35% reduction in the Company's total workforce, including approximately fifty full-time employees. The remaining $692 represents a write-down of net assets, the loss associated with underutilized lease obligations and legal and other expenses associated with reducing the Company's workforce. At December 31, 2001, approximately $544 of all restructuring costs had yet to be paid, primarily because certain terminated employees had employment agreements which provide for monthly severance benefits beyond 2001.

5. DEBT

Debt consists of the following:

| | DECEMBER 31, | |
|---|---|---|
| | 2001 | 2000 |
| Secured note payable, thirty monthly payments with final payment due April 2004; interest payable at 10.2% | $ 2,799 | $ -- |
| Unsecured note payable, nine monthly payments with final payment due August 2002; interest payable at 5.4% | 335 | -- |
| Capital lease obligation, with final payment due May 2001 | -- | 7 |
| Current portion | (1,454) | (7) |
| Non-current debt | $ 1,680 | $ -- |

The secured note payable is fully collateralized by the Company's property, plant and equipment and contains a covenant requiring a minimum cash and investment balance. At December 31, 2001, the Company was in compliance with this covenant. Interest expense associated with debt obligations for 2001, 2000 and 1999 was $79, $5 and $34, respectively.

6. STOCKHOLDERS' EQUITY

During 1996 and 1995, the Company issued 5,232 shares of convertible Series A Preferred Stock with a par value of $0.001 per share for $3,900, net of offering costs. During 1996, the Company issued 3,706 shares of convertible Series B Preferred Stock with a par value of $0.001 per share for $18,400, net of offering costs. No preferred dividends were declared or paid from the date of inception (July 12, 1995) through the date of conversion





6. STOCKHOLDERS' EQUITY (CONTINUED)

of all Preferred Stock into Common Stock on a one-for-one basis in connection with the closing of the Company's initial public offering (the "IPO"). The Company's certificate of incorporation authorizes the Board of Directors, without further action by the stockholders, to issue Preferred Stock, in one or more series and to fix the rights, priorities, preferences, qualifications, limitations and restrictions, including dividend rights, conversion rights, voting rights, terms of redemption, terms of sinking funds and liquidation preferences of each series of Preferred Stock issued.

On November 6, 1996, the Company completed its IPO of 4,533 shares of Common Stock at $10.00 per share. The net proceeds of this offering, after underwriting discounts and costs in connection with the sale and distribution of the securities, were approximately $41,000.

On June 6, 1997, the Company issued 2,000 shares of Common Stock for $30,000, or a price of $15.00 per share. Net proceeds to the Company from this private offering were approximately $29,400. Pursuant to the purchase agreement, these shares were registered on January 23, 1998 with the Securities and Exchange Commission.

On April 15, 1998, the Company completed registration of 4,025 shares of Common Stock at $15.00 per share with the Securities and Exchange Commission. The total proceeds of this public offering, net of offering costs, were approximately $55,800.

On December 24, 1998, the Company issued 170 shares of convertible Series A Preferred Stock with a par value of $0.001 per share for $100.00 per share in a private offering to accredited institutional investors. The total proceeds of this offering, net of offering costs, were approximately $15,600. On May 14, 1999, all 170 shares were converted to 1,700 shares of Common Stock upon the approval of the issuance of preferred shares by the stockholders of the Company.

On December 30, 1998, the Company issued 4,800 shares of Common Stock for $10.00 per share in a private offering to accredited investors. The total proceeds of this offering, net of offering costs, were approximately $44,400. Pursuant to the terms of this offering, a registration statement covering the resale of these shares was declared effective by the Securities and Exchange Commission on December 31, 1998.

On August 3, 1999, the Company completed its worldwide strategic alliance (the "Abbott Alliance") with Abbott Laboratories ("Abbott") resulting in Abbott

purchasing 6,571 shares of Common Stock at $18.00 per share. Net proceeds to the Company were approximately $115,861.

On March 1, 2001, the Company issued 7,700 shares of Common Stock for $6.00 per share in a private offering to a limited number of qualified institutional buyers and large institutional accredited investors. The total proceeds of this offering, net of offering costs, were approximately $43,475. Additionally, the Company issued 200 shares of convertible Series B Preferred Stock for $60.00 per share in a private offering to a small number of qualified institutional buyers and large institutional accredited investors on March 9, 2001. This sale yielded total net proceeds of approximately $10,900. On May 18, 2001, Triangle's stockholders' approved the issuance of the Series B preferred stock, which triggered the conversion of each preferred share into ten shares of our Common Stock. Pursuant to the terms of this offering, a registration statement covering the resale of these shares was declared effective by the Securities and Exchange Commission on July 11, 2001.

On August 24, 2001, the Company entered into a purchase agreement with Warburg Pincus Private Equity VIII, L.P. ("Warburg Pincus") for the sale of 28,302 shares of Common Stock in a two-stage private placement at a purchase price of $2.65 per share. On the same day, the first closing of the private placement occurred and the Company issued 9,628 shares of Common Stock for net proceeds totaling approximately $23,975. On October 10, 2001, the second closing of the remaining 18,674 shares of Common Stock occurred, resulting in net proceeds





6. STOCKHOLDERS' EQUITY (CONTINUED)

totaling approximately $46,550. On the same day, the Company's certificate of incorporation was amended to modify the number of authorized capital stock to 175,000 shares of Common Stock, $0.001 par value per share, and 10,000 shares of Preferred Stock, $0.001 par value per share. Pursuant to the purchase agreement, the Company registered the Common Stock sold in both closings, elected two individuals nominated by Warburg Pincus to the Board of Directors, and granted Warburg Pincus rights to participate in certain future sales of Common Stock, as long as Warburg Pincus owns approximately 5,846 shares of Common Stock.

At December 31, 2001 and 2000, the Company had outstanding warrants entitling the holder to acquire 300 shares of Common Stock at $13.00 per share.

7. EMPLOYEE BENEFIT PLANS

EMPLOYEE STOCK PURCHASE PLAN

The Company's Employee Stock Purchase Plan (the "Purchase Plan") became effective November 1, 1996. The Purchase Plan is designed to allow eligible employees of the Company to purchase shares of Common Stock, at semi-annual intervals, through periodic payroll deductions under the Purchase Plan. A reserve of 300 shares of Common Stock has been established for this purpose. The Purchase Plan is implemented in a series of successive offering periods, each with a maximum duration of twenty-four (24) months. Payroll deductions may not exceed 10% of the participant's base salary for each semi-annual period of participation nor exceed $25 per annum, and the accumulated payroll deductions

will be applied to the purchase of shares on the participant's behalf on each semi-annual purchase date (the last business day of February and August each year, at a purchase price per share not less than 85% of the lower of (i) the fair market value of the Common Stock on the participant's entry date into the offering period or (ii) the fair market value of the Common Stock on the semi-annual purchase date). Should the fair market value of the Common Stock on any semi-annual purchase date be less than the fair market value of the Common Stock on the first day of the offering period, then the current offering period will automatically end and a new twenty-four month offering period will begin, based on the lower fair market value. The shares vest immediately upon issuance.

During 2001, 2000 and 1999, the Company issued 57, 45 and 39 shares, respectively, under the Purchase Plan. At December 31, 2001, the Company held payroll deductions of approximately $45 which will be used to purchase shares of Common Stock in 2002. The Purchase Plan had an insignificant impact on the Company's 2001, 2000 and 1999 pro forma fair value disclosure as required under SFAS 123.

SALARY INVESTMENT OPTION GRANT PROGRAM

The Company's Salary Investment Option Grant Program (the "Investment Plan") allows executive officers and other highly compensated employees of the Company to reduce their base salary for that calendar year by a specified dollar amount not less than $10 nor more than $50. Participants are issued a non-statutory option to purchase that number of shares of Common Stock determined by dividing the total salary reduction amount by an amount equal to one-third of the fair market value per share of Common Stock on the grant date. The option will be exercisable at a price per share equal to the difference between the amount paid by the optionee for the option and the fair market value of the option shares on the grant date. As a result, upon exercise of the options issued under the Investment Plan, the optionee will have paid 100% of the fair market value of the option shares as of the grant date. The option will vest and become exercisable in a series of twelve (12) equal monthly installments over the calendar year for which the salary reduction is in effect and will vest and become fully exercisable on specified changes in the ownership or control of the Company. Options have a maximum term of ten years from the date of grant.





7. EMPLOYEE BENEFIT PLANS (CONTINUED)

DIRECTOR COMPENSATION

All eligible non-employee directors received an option to purchase 7.5 shares of Common Stock for each year of the director's Board of Directors term plus an additional 7.5 shares for those directors who have not served previously. These options have an exercise price equal to 100% of the fair market value of the Common Stock on the grant date and will become exercisable in annual installments after the completion of each year of service following such grant. Options vest on the day immediately preceding the next annual Board of Directors meeting and have a maximum term of ten years from the date of grant, or one year from the cessation of Board of Directors service.

401(K) PENSION PLAN

The Company sponsors a qualified defined contribution pension plan which is available to substantially all full-time employees. This 401(k) plan provides for employer matching contributions based on employee participation. The total expense under this plan was $261, $260 and $184 for 2001, 2000 and 1999, respectively.

1996 STOCK INCENTIVE PLAN

The Company's 1996 Stock Incentive Plan (the "1996 Plan") serves as the successor equity incentive program to the Company's 1996 Stock Option/Stock Issuance Plan. The 1996 Plan became effective on August 30, 1996 and 2,200 options of Common Stock were authorized for issuance. On May 15, 1998, an additional 1,000 options were authorized for issuance with an automatic increase provision whereby on January 1, 1999, 2000 and 2001 four percent of the total number of shares of Common Stock issued and outstanding, as of December 31 of the preceding year, will be authorized for issuance up to an annual maximum limitation of 1,000. On May 18, 2001, an additional amendment to the 1996 Plan was approved, whereby the number of shares of Common Stock reserved for issuance increases automatically by 1,500 shares on January 1, 2002 and on January 1, 2003. In no event may any one participant receive option grants or direct stock issuances for more than 500 shares in the aggregate per calendar year. Options generally vest over a four-year period and have a maximum term of ten years from the date of grant.

In accordance with the provisions of SFAS 123, the Company has chosen to continue to account for stock-based compensation using the intrinsic value method required by APB 25.

The following table summarizes the stock option activity for the Company's plans:

| | NUMBER OF SHARES | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVERAG FAIR VALUE |
|---|---|---|---|
| Options outstanding, December 31, 1998 .... | 2,481 | $ 10.895 | |
| Granted at fair value ..... | 991 | 13.774 | $ 9.146 |
| Exercised ..... | (256) | 0.754 | |
| Forfeited ..... | (83) | 17.406 | |
| Options outstanding, December 31, 1999 .... | 3,133 | 12.460 | |
| Granted below fair value ..... | 24 | 8.865 | $ 1.858 |
| Granted at fair value ..... | 1,321 | 7.563 | $ 5.362 |
| Granted above fair value ..... | 213 | 16.712 | $ 0.936 |
| Exercised ..... | (225) | 1.683 | |
| Forfeited ..... | (621) | 14.853 | |
| Options outstanding, December 31, 2000 .... | 3,845 | 11.234 | |
| Granted at fair value ..... | 1,555 | 3.609 | $ 2.435 |
| Exercised ..... | (141) | 2.040 | |
| Forfeited ..... | (675) | 10.516 | |
| Options outstanding, December 31, 2001 .... | 4,584 | $ 9.037 | |

TRIANGLE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

7. EMPLOYEE BENEFIT PLANS (CONTINUED)

The following table summarizes information concerning options outstanding at December 31, 2001 and 2000:

| | NUMBER OF SHARES | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVER REMAINING CONTRACTUAL L (IN YEARS) |
|---|---|---|---|
| Options outstanding- | | | |
| Price range: | | | |
| $0.075 - $3.600 | 1,349 | $ 2.548 | 8.86 |
| $3.620 - $6.313 | 973 | 5.651 | 8.68 |
| $6.875 - $13.250 | 1,265 | 11.120 | 7.47 |
| $13.406 - $20.750 | 743 | 16.718 | 6.21 |
| $23.625 - $23.625 | 254 | 23.625 | 5.48 |
| Options outstanding, December 31, 2001 | 4,584 | $ 9.037 | 7.82 |
| Exercisable options outstanding- | | | |
| Price range: | | | |
| $0.075 - $3.600 | 231 | $ 0.279 | |
| $3.620 - $6.313 | 376 | 5.701 | |
| $6.875 - $13.250 | 801 | 10.988 | |
| $13.406 - $20.750 | 690 | 16.678 | |
| $23.625 - $23.625 | 254 | 23.625 | |
| Exercisable options outstanding, December 31, 2001 | 2,352 | $ 12.123 | |
| Exercisable options outstanding, December 31, 2000 | 1,842 | $ 12.428 | |

To determine the impact of SFAS 123, the fair value of each option grant is estimated on the date of grant using the Black-Scholes valuation model with the following assumptions:

| | DECEMBER 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Expected dividend yield | 0.00% | 0.00% | 0.00% |
| Expected stock price volatility | 93.00% | 92.00% | 80.00% |
| Risk-free interest rate | 4.01% | 5.17%-5.22% | 6.14-6.19% |
| Expected life of options | 4 years | 4-5 years | 4-5 years |

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

For purposes of pro forma disclosures, the estimated fair value of equity instruments is amortized to expense over their respective vesting period. If the Company had elected to recognize compensation expense based on the fair value of stock-based instruments at the grant date, as prescribed by SFAS 123, its pro forma net loss and net loss per common share would have been as follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Net loss - as reported | $ (75,926) | $ (109,525) | $ (104,621) |
| Net loss - pro forma | $ (81,543) | $ (117,238) | $ (109,078) |
| Net loss per common share - as reported | $ (1.40) | $ (2.87) | $ (3.18) |
| Net loss per common share - pro forma | $ (1.51) | $ (3.08) | $ (3.31) |





## 8. LICENSING AGREEMENTS

As of December 31, 2001, the Company has multiple license agreements for its drug candidates as well as collaborative agreements with specific third parties to assist in the identification and development of other novel drug candidates. In the aggregate, these agreements, with the exception of Coactinon which was formally terminated in January 2002, may require future payments of up to $57,250 contingent upon the achievement of development milestones, up to $30,000 upon the achievement of sales milestones, and $2,188 of future research and development payments. The Company is also obligated to issue 250 shares of Common Stock if development milestones are achieved regarding compounds for the treatment of hepatitis B obtained in the Avid Corporation ("Avid") acquisition. Additionally, the Company will pay royalties based upon 7.5% to 22% of net sales of each licensed product depending on drug candidate and net sales volume. The Company's license agreements also require minimum royalty payments commencing three years after regulatory approval of the licensed compound. Milestone payments are typically contingent on completing phases of clinical trials and receiving registrations for compounds. Depending on the Company's success and timing in obtaining regulatory approval, aggregate annual minimum royalties and annual license preservation fees could range from $50 (if only a single drug candidate is approved for one indication) to $47,000 (if all drug candidates are approved for all indications) under the Company's existing license agreements.

## 9. INCOME TAXES

There is no current income tax provision or benefit recorded in any period as the Company has generated net operating losses for income tax purposes. There is no deferred income tax provision or benefit recorded in any period as the Company is in a net deferred tax asset position for which a full valuation allowance has been recorded due to the uncertainty of its realization.

At December 31, 2001, 2000 and 1999, the Company had net operating loss carryforwards of approximately $341,664, $265,279 and $155,344, respectively, and research credit carryforwards of approximately $12,916, $10,895 and $8,249, respectively, which will expire in years 2006 to 2021. The Company's ability to

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

utilize its carryforwards may be subject to an annual limitation in future periods pursuant to the "change in ownership" provisions under Section 382 of the Internal Revenue Code.

In connection with the acquisition of Avid, the Company acquired transferable net operating loss carryforwards, research and development credits and capitalized start-up costs which may be used to offset certain future income. Net operating loss carryforwards associated with Avid will have an annual limitation on the amount available to reduce certain future taxable income.

The components of deferred taxes are as follows:

| | DECEMBER 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Loss carryforwards | $ 134,906 | $ 104,918 | $ 61,439 |
| Research tax credit | 12,916 | 10,895 | 8,249 |
| License fees | 9,218 | 7,805 | 7,347 |
| Deferred revenue | 7,354 | 9,658 | 9,887 |
| Accrued liabilities and reserves | 4,447 | 3,181 | 2,912 |
| Start-up costs | 226 | 567 | 907 |
| Deferred tax assets | 169,067 | 137,024 | 90,741 |
| Deferred tax assets valuation allowance | (169,067) | (137,024) | (90,741) |
| Net deferred tax asset | $ -- | $ -- | $ -- |





10. AVID ACQUISITION

On August 28, 1997, the Company acquired Avid in a merger accounted for as a purchase transaction. Pursuant to the merger agreement, Triangle issued 400 shares of Common Stock in exchange for all outstanding capital stock of Avid. In connection with the acquisition, the Company incurred a charge of $11,261 for acquired in-process research and development. The Company subsequently issued another 600 shares of Common Stock for milestone obligations and related milestone extensions associated with the development of mozenavir dimesylate as additional consideration to the former Avid shareholders. Issuance of these shares resulted in additional purchased research and development charges recorded in 1999, 2000 and 2001. These in-process research and development charges were based upon the fair market value of Triangle Common Stock at the date upon which an obligation to the former Avid shareholders existed. The 2001 issuance of 100 shares satisfies all current and any future obligations in regards to contingent development milestones for mozenavir dimesylate. There, however, remains a contingency for the issuance of 250 shares of Common Stock if development milestones are achieved regarding compounds for the treatment of hepatitis B obtained in the acquisition, although the Company is not currently

developing these compounds. Issuance of any additional contingent shares will be recorded as additional purchase price and will be allocated upon resolution of the underlying contingency. The operating results of Avid have been included in the Company's consolidated financial statements from its acquisition. Avid's principal asset consisted of worldwide license rights to mozenavir dimesylate.

11. STRATEGIC ALLIANCE WITH ABBOTT LABORATORIES

In August 1999, the Company completed a worldwide strategic alliance with Abbott for several of its antiviral compounds. Under the terms of the Abbott Alliance, Triangle and Abbott will collaborate with respect to the clinical development, registration, distribution and marketing of various proprietary pharmaceutical products for the prevention and treatment of HIV and hepatitis B virus. In the United States, Triangle and Abbott will co-promote three Triangle drug candidates currently in active development for HIV and/or hepatitis B, Coviracil, amdoxovir and clevudine, and Abbott's HIV protease inhibitor, Kaletra. Outside the United States, Abbott will have exclusive sales and marketing rights for the three Triangle antiviral compounds. Triangle and Abbott will share profits and losses for the Triangle drug candidates. Triangle will receive detailing fees and commissions on incremental sales it generates for Kaletra, although Triangle has not begun promoting Kaletra. In addition, Abbott has the right of first discussion to market future Triangle compounds. The Abbott Alliance provided for non-contingent research and development reimbursement of $31,714, which has been received, and currently provides for up to $120,000 of contingent development milestone payments and the sharing of future commercialization costs. In addition, Abbott initially purchased approximately 6,571 shares of Triangle Common Stock at $18.00 per share which resulted in net proceeds to the Company of $115,861, and has subsequently purchased another 1,367 shares which resulted in net proceeds of $8,208. Pursuant to the terms of the Abbott Alliance, Abbott has the right to purchase additional amounts of Triangle Common Stock up to a maximum aggregate percentage of 21% and has certain rights to purchase shares directly from the Company in order to maintain a certain ownership interest in Triangle, also known as antidilution protection. The Abbott Alliance provides access to Abbott's international and domestic infrastructure to market and distribute products receiving regulatory approval, global manufacturing capabilities, drug development assistance, United States co-promotion rights to Kaletra, as well as financial support to help fund the continued development of our portfolio of drug candidates.

12. RELATED PARTY TRANSACTIONS

The Company has two outside directors on its Board of Directors which are affiliated with companies with which Triangle conducts business operations and whose companies have investments in Triangle Common Stock. One director is affiliated with Abbott and the other has an ownership interest in various companies that Triangle has utilized, and continues to utilize, in the completion of its clinical studies. At December 31, 2001, these companies owned approximately 5%, and Abbott owned approximately 10% of Triangle's outstanding Common Stock. As of December 31, 2001 and 2000, the Company had accounts payable outstanding to these companies performing clinical services of approximately $207 and $1,631, respectively, and incurred approximately $1,035, $6,217 and $2,763 during 2001, 2000 and 1999, respectively, in development expense for services provided.

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

12. RELATED PARTY TRANSACTIONS (CONTINUED)

In association with the Abbott Alliance, the Company utilizes Abbott for assistance primarily in drug development and manufacture and shares expenses under a profit and loss calculation for Triangle drug candidates in the Abbott Alliance. Accordingly, the Company had accounts payable of $2,645 and $6,005 at December 31, 2001 and 2000, respectively, and had incurred approximately $5,014, $18,388 and $4,676 during 2001, 2000 and 1999, respectively, for development services performed by Abbott. Under the profit and loss calculation, the Company had a receivable of $480 and $413 at December 31, 2001 and 2000, respectively, and accordingly 2001, 2000 and 1999 marketing expense was reduced by $421, $1,416 and $1,518, respectively, thereby reducing selling, general and administrative expenses. The Company recognized $5,795 and $7,294 of collaborative revenue during 2001 and 2000, respectively, associated with the amortization of research and development expense reimbursement.

Triangle's Chairman and Chief Executive Officer, Dr. David W. Barry, served on the Board of Directors of Dynavax, and another Triangle non-employee director is an executive officer with an investment organization which has a greater than 5% investment in Dynavax. In association with the strategic license and collaborative agreement with Dynavax, the Company utilized Dynavax for assistance in conducting the initial clinical trial associated with the Company's immunostimulatory pharmaceutical candidates. Accordingly, the Company had accounts payable of $313 and $500 at December 31, 2001 and 2000, respectively, and had incurred approximately $2,063 and $1,000 in expenses during 2001 and 2000, respectively, for development services. In April 2000, the Company purchased $2,000 of Dynavax Preferred Stock, and subsequently, in 2001, recorded a $1,000 loss based upon an impairment of the investment.

13. STOCKHOLDER RIGHTS PLAN

On January 29, 1999, the Board of Directors adopted a "Stockholder Rights Plan" in which Preferred Stock Purchase Rights were distributed as a dividend at the rate of one right per share of Common Stock and ten rights per share of Series A Preferred Stock (i.e., the equivalent of one right per share of Common Stock issuable upon the conversion of the Series A Preferred Stock), held as of February 16, 1999. Each right entitles the holder to acquire one-thousandth of a share of $0.001 par value Series B Junior Participating Preferred Stock, upon a third party acquiring beneficial ownership of 15% or more of the Company's Common Stock, without the consent of the Board of Directors, at a price of $100.00 per right. The Company can redeem the rights for $0.001 per right at the discretion of the Board of Directors. The Stockholder Rights Plan is designed to deter a party from gaining control of the Company without offering a fair price to all stockholders and should encourage a party to negotiate with the Board of Directors prior to attempting to acquire the Company.

14. COMMITMENTS AND CONTINGENCIES

The Company is indirectly involved in several opposition and interference proceedings and two lawsuits filed in Australia regarding the patent rights related to its licensed drug candidate, amdoxovir. Although the Company is not a named party in any of these proceedings, it is obligated to reimburse its licensors for certain legal expenses associated with these proceedings. In one of these patent opposition proceedings, on November 8, 2000, the Australian Patent Office held that several patent claims of Emory University ("Emory") directed to amdoxovir are not patentable over an earlier opposing patent. Emory has appealed this decision of the Australian Patent Office to the Australian Federal Court. If Emory and the Company are unsuccessful in the appeal, then the Company will not be able to sell amdoxovir in Australia without a license, which may not be available on reasonable terms or at all. The Company cannot predict

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

the outcome of these proceedings. The Company believes that an adverse judgment would not result in a material financial obligation to the Company, nor would the Company have to recognize an impairment under SFAS No. 121 "ACCOUNTING FOR IMPAIRMENT OF LONG-LIVED ASSETS AND LONG-LIVED ASSETS TO BE DISPOSED OF" as no amounts have been capitalized related to this drug candidate. However, any development in these proceedings adverse to the Company's interests could have a material adverse effect on the Company's future operations.





14. COMMITMENTS AND CONTINGENCIES (CONTINUED)

The Company enters into contractual arrangements regarding clinical and toxicology studies in the development of its drug candidates. At December 31, 2001, the Company estimates its commitment to be approximately $20,617 under these agreements; however, this estimate is dependent upon the results of the underlying studies and certain other variable components. Additionally, the Company has entered into agreements with third parties to provide drug substance to satisfy its drug development requirements and to provide for the potential commercial launch of its drug candidates. At December 31, 2001, the Company estimates its commitment for drug substance to be approximately $5,000. Similar to the clinical and toxicology studies commitment, this estimate is subject to a number of variables that may result in the actual obligation differing from management's estimate.

15. SUMMARY QUARTERLY FINANCIAL DATA (UNAUDITED)

| | 2001 | | | | | |
|---|---|---|---|---|---|---|
| | FIRST QUARTER | SECOND QUARTER | THIRD QUARTER | FOURTH QUARTER | FIRST QUARTER | SECOND QUARTER |
| Revenues | $ 1,744 | $ 1,744 | $ 1,271 | $ 1,035 | $ 1,982 | $ 1,824 |
| Loss from Operations | (23,898) | (22,163) | (18,970) | (13,584) | (33,662) | (28,752 |
| Net Loss | (22,858) | (21,163) | (18,197) | (13,708) | (31,386) | (26,758 |
| Basic and Diluted Loss per Common Share | $ (0.55) | $ (0.45) | $ (0.35) | $ (0.18) | $ (0.83) | $ (0.70 |

16. SUBSEQUENT EVENT (UNAUDITED)

In January 2002, the Company's Chief Executive Officer and Chairman of the Board, Dr. David W. Barry, died unexpectedly. The Board of Directors is currently conducting a search for a qualified replacement. Additionally, the Company has filed a claim under a keyman insurance policy and expects a $10,000 settlement in the first quarter of 2002.



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

(a) Identification of Directors. The information under the heading "Election of Directors," appearing in the Proxy Statement, is incorporated herein by reference.

(b) Identification of Executive Officers. The information under the heading "Executive Officers," appearing in the Proxy Statement, is incorporated herein by reference.

(c) Section 16(a) Beneficial Ownership Reporting Compliance. The information under the heading "Section 16(a) Beneficial Ownership Reporting Compliance," appearing in the Proxy Statement, is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information under the heading "Executive Compensation and Other Information," appearing in the Proxy Statement, is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information under the heading "Principal Stockholders," appearing in the Proxy Statement, is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information under the heading "Certain Relationships and Related Transactions," appearing in the Proxy Statement, is incorporated herein by reference.



PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) (1) Financial Statements

The financial statements of the Company are included herein as required under Item 8 of this Annual Report on Form 10-K. See Index to Consolidated Financial Statements on page 47.

(2) Financial Statement Schedules

All schedules for which provision is made in the applicable accounting

regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

(b) Reports on Form 8-K

On October 10, 2001, we filed a current report on Form 8-K dated October 10, 2001, announcing the approval of an amendment to our Second Restated Certificate of Incorporation, and the completion of a private placement of 18,673,885 newly issued shares of common stock to a group of investors led by Warburg Pincus.

On December 7, 2001, we filed a current report on Form 8-K dated November 30, 2001, announcing the signing of a Master Loan and Security Agreement with Wells Fargo Equipment Finance, Inc.

On January 18, 2002, we filed a current report on Form 8-K dated January 17, 2002, announcing our plans to file an NDA for Coviracil for the treatment of HIV in September 2002 and the discontinuation of development of Coactinon.

On January 29, 2002, we filed a current report on Form 8-K dated January 28, 2002, announcing the death of David W. Barry, Chairman and Chief Executive Officer.

(c) Exhibits

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.1(a) | Restated Certificate of Incorporation of the Company. |
| 3.2(a) | Second Restated Certificate of Incorporation of the Company. |
| 3.3 | Amendment to Second Restated Certificate of Incorporation (filed as Exhibit 4.1 to the Company's Form 8-K filed October 10, 2001). |
| 3.4 | Bylaws of the Company, as amended (filed as Exhibit 3.3 to the Company's Form S-1 filed September 9, 1996). |
| 3.5 | Restated Bylaws of the Company (filed as Exhibit 3.4 to the Company's Form S-1 filed September 9, 1996). |
| 3.6 | Certificate of Designations, Preferences and Rights of the Series B Junior Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware (filed as Exhibit 3.6 to the Company's Form 10-K filed March 19, 1999). |



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| 3.7 | Certificate of Designations, Preferences and Rights of the Series B Preferred Stock, as filed with the Secretary of State of the State of Delaware (filed as Exhibit 4.1 to the Company's Form 8-K filed March 21, 2001). |
| 4.1(a) | Form of Certificate for Common Stock. |
| 4.2(a) | Form of Restricted Stock Purchase Agreement. |
| 4.3 | Form of Purchase Agreement made as of January 30, 2001, between the Company and each of the investors with whom the stock was placed |

(filed as Exhibit 4.2 to the Company's Form S-3/A filed February 27, 2001).

4.4 Form of Purchase Agreement with respect to the Series B Preferred Stock made as of January 30, 2001 between the Company and each of the investors with whom the stock was placed (filed as Exhibit 10.1 to the Company's Form 8-K filed March 21, 2001).

4.5 Amendment to Rights Agreement between America Stock Transfer & Trust Company and the Company, dated August 24, 2001 (filed as Exhibit 4.1 to the Company's Form 8-K filed August 24, 2001).

10.2(a) Form of Employee Proprietary Information Agreement.

10.12(a) Sublease between the Company and Eli Lilly, dated January 18, 1996.

10.18(a) Sublease Amendment between the Company and Eli Lilly, dated March 1, 1996.

10.19(a) License Agreement among the Company, Emory University and the University of Georgia Research Foundation, Inc. for compound amdoxovir (DAPD), dated March 31, 1996.

10.22(a) License Agreement between the Company and Emory University for Coviracil (FTC), dated April 17, 1996.

10.31(a) Second Amendment to Sublease between the Company and Eli Lilly and Company, dated August 2, 1996.

10.40(a) Employee Stock Purchase Plan.

10.41(a) Form of Indemnification Agreement between the Company and each of its directors.

10.42(a) Form of Indemnification Agreement between the Company and each of its officers.

10.44(a) Form of Waiver of Registration Rights, dated September 5, 1996.

10.47 License Agreement between the Company and Mitsubishi Chemical Corporation dated June 17, 1997 (filed as Exhibit 10.3 to the Company's Form 10-Q filed August 14, 1997).

10.48 License Agreement dated as of February 27, 1998, between the Company and Bukwang Pharm. Ind. Co., Ltd. (filed as Exhibit 10.51 to the Company's Form 10-K filed March 10, 1998).

10.49 Amended and Restated 1996 Stock Incentive Plan (as amended and restated through March 27, 1998) (filed as Exhibit 99.1 to the Company's Form S-8 filed June 5, 1998).

10.50 Amended and Restated 1996 Stock Incentive Plan - Form of Stock Option Agreement (filed as Exhibit 99.3 to the Company's Form S-8 filed June 5, 1998).



10.51 Amended and Restated 1996 Stock Incentive Plan - Form of Addendum to Stock Option Agreement (Involuntary Termination Following Corporate Transaction) (filed as Exhibit 99.4 to the Company's Form S-8 filed

June 5, 1998).

10.52 Amended and Restated 1996 Stock Incentive Plan - Form of Addendum to Stock Option Agreement (Involuntary Termination Following Change in Control) (filed as Exhibit 99.5 to the Company's Form S-8 filed June 5, 1998).

10.53 Amended and Restated 1996 Stock Incentive Plan - Form of Stock Issuance Agreement (filed as Exhibit 99.6 to the Company's Form S-8 filed June 5, 1998).

10.54 Amended and Restated 1996 Stock Incentive Plan - Form of Automatic Stock Option Agreement (filed as Exhibit 99.8 to the Company's Form S-8 filed June 5, 1998).

10.55 Amended and Restated 1996 Stock Incentive Plan - Form of Salary Investment Stock Option Agreement (filed as Exhibit 99.11 to the Company's Form S-8 filed June 5, 1998).

10.56 Rights Agreement, dated as of February 1, 1999, between the Company and American Stock Transfer & Trust Company, which includes the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series B Preferred Shares as Exhibit C (filed as Exhibit 4 to the Company's Form 8-K filed February 10, 1999).

10.57 Form of Employment Agreement among the Company and each officer of the Company. (filed as Exhibit 10.63 to the Company's Form 10-K filed March 19, 1999).

10.58 Third Amendment to Sublease between the Company and Eli Lilly and Company, dated as of February 11, 1998. (filed as Exhibit 10.64 to the Company's Form 10-K filed March 19, 1999).

10.59 Collaboration Agreement between the Company and Abbott Laboratories dated as of June 2, 1999 (filed as Exhibit 2.1 to the Company's Form 8-K/A filed November 3, 1999).

10.60 Co-Promotion Agreement between the Company and Abbott Laboratories dated as of June 2, 1999 (filed as Exhibit 2.2 to the Company's Form 8-K/A filed November 3, 1999).

10.61 Triangle Pharmaceuticals, Inc. Common Stock Purchase Agreement between the Company and Abbott Laboratories dated as of June 2, 1999 (filed as Exhibit 99(a)(1) to Abbott Laboratories' Schedule 13D filed June 11, 1999).

10.62 Triangle Pharmaceuticals, Inc. Stockholder Rights Agreement between the Company and Abbott Laboratories dated as of June 2, 1999 (filed as Exhibit 99(a)(2) to Abbott Laboratories' Schedule 13D filed June 11, 1999).

10.63 Amendment to Rights Agreement between the Company and Abbott Laboratories dated as of June 2, 1999 (filed as Exhibit 4.1 to the Company's Form 8-K filed June 18, 1999).

10.64 Amendment to Rights Agreement between the Company and American Stock Transfer & Trust Company dated as of June 2, 1999 (filed as Exhibit 1 to the Company's Form 8-A12G/A filed June 18, 1999).

10.65 Exclusive License Agreement among the Company, Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University dated May 6, 1999 (filed as Exhibit 10.1 to the Company's

Form 10-Q/A filed November 3, 1999).

10.66 Settlement Agreement among the Company, Emory University, Dr. David W. Barry, Glaxo Wellcome plc, Glaxo Wellcome Inc., Glaxo Group Limited and The Wellcome Foundation Limited dated May 6, 1999 (filed as Exhibit 10.2 to the Company's Form 10-Q/A filed November 3, 1999).



10.67 Amendment to License Agreement between the Company and Bukwang Pharm. Ind. Co., Ltd. dated April 1, 1999 (filed as Exhibit 10.3 to the Company's Form 10-Q/A filed November 3, 1999).

10.68 First Amendment to License Agreement between the Company and Emory University dated May 6, 1999 (filed as Exhibit 10.4 to the Company's Form 10-Q/A filed November 3, 1999).

10.69 Supply and Manufacturing Agreement by and between Abbott Laboratories and the Company dated August 3, 1999 (filed as Exhibit 10.1 to the Company's Form 10-Q filed November 12, 1999).

10.70 Declaration of Registration Rights, dated as of June 30, 1997 (filed as Exhibit 10.4 to the Company's Form 10-Q filed May 15, 2000).

10.71 License Agreement between Dynavax Technologies Corporation and the Company, dated as of March 31, 2000 (filed as Exhibit 10.5 to the Company's Form 10-Q filed May 15, 2000).

10.72 First Amendment to License Agreement between Emory University, the University of Georgia Research Foundation, Inc. and the Company, dated July 10, 2000 (filed as Exhibit 10.1 to the Company's Form 10-Q filed November 14, 2000).

10.73 Second Amendment to License Agreement between Emory University and the Company, dated July 10, 2000 (filed as Exhibit 10.2 to the Company's Form 10-Q filed November 14, 2000).

10.74 Amendment to License Agreement between Bukwang Pharm. Ind. Co., Ltd. and the Company, dated September 5, 2000 (filed as Exhibit 10.4 to the Company's Form 10-Q filed November 14, 2000).

10.75 First Amendment to Employment Agreement between Carolyn Underwood and the Company, dated April 12, 2000 (filed as Exhibit 10.91 to the Company's Form 10-K filed February 26, 2001).

10.76 Amendment to License Agreement between Mitsubishi-Tokyo Pharmaceuticals, Inc. and the Company, dated January 1, 2001 (filed as Exhibit 10.93 to the Company's Form 10-K filed February 26, 2001).

10.77 Form of Common Stock Purchase Agreement, dated January 30, 2001 (filed as Exhibit 10.94 to the Company's Form 10-K filed February 26, 2001).

10.78 Amendment to Co-Promotion Agreement between Abbott Laboratories and the Company, dated February 12, 2001 (filed as Exhibit 10.95 to the Company's Form 10-K filed February 26, 2001).

10.79 Amendment to Triangle Pharmaceuticals, Inc. 1996 Stock Incentive

Plan (as amended and restated through March 27, 1998) dated May 18, 2001 (filed as Exhibit 10.1 to the Company's Form 10-Q filed August 10, 2001).

10.80 Purchase Agreement between Warburg Pincus Private Equity VIII, L.P. and the Company, dated August 24, 2001 (filed as Exhibit 10.1 to the Company's Form 8-K filed August 24, 2001).

10.81 Standstill Agreement between Warburg Pincus Private Equity VIII, L.P. and the Company, dated August 24, 2001 (filed as Exhibit 10.3 to the Company's Form 8-K filed August 24, 2001).

10.82 Form of Purchase Agreement, between the Company and each of QFinance, Inc., Caduceus Capital II, L.P., Winchester Global Trust Company Limited as Trustee for Caduceus Capital Trust, PW Eucalyptus Fund, L.L.C. and PW Eucalyptus Fund, Ltd., each dated August 30, 2001 (filed as Exhibit 10.1 to the Company's Form 8-K filed October 10, 2001).

10.83 Master Loan and Security Agreement, between Wells Fargo Equipment Finance, Inc. and the Company, dated November 30, 2001 (filed as Exhibit 10.1 to the Company's Form 8-K filed December 7, 2001).



23.1 Consent of PricewaterhouseCoopers LLP, Independent Accountants.

24.1 Power of Attorney. Reference is made to page 74.

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(a) Incorporated by reference to the same-numbered exhibit to the Company's Registration statement on Form S-1 filed September 9, 1996.

SUPPLEMENTAL INFORMATION

Copies of the Registrant's Proxy Statement for the 2002 Annual Meeting of Stockholders and copies of the form of proxy to be used for such Annual Meeting will be furnished to the Securities and Exchange Commission prior to the time they are distributed to the Registrant's stockholders.



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 25, 2002 TRIANGLE PHARMACEUTICALS, INC.

By: /s/ Chris A. Rallis

Chris A. Rallis
President and Chief Operating Officer

POWER OF ATTORNEY

Know all men by these presents, that each person whose signature appears below constitutes and appoints Chris A. Rallis or Robert F. Amundsen, Jr., his or her attorney-in-fact, with power of substitution in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the attorney-in-fact or his or her substitute or substitutes may do or cause to be done by virtue hereof.

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

| SIGNATURE | TITLE | DATE |
|---|---|---|
| /s/ Chris A. Rallis<br>Chris A. Rallis | Director, President and Chief Operating Officer<br>(Principal Executive Officer) | March 25, 2002 |
| /s/ Robert F. Amundsen, Jr.<br>Robert F. Amundsen, Jr. | Executive Vice President and Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 25, 2002 |
| /s/ Anthony B. Evnin<br>Anthony B. Evnin | Director | March 25, 2002 |
| /s/ Standish M. Fleming<br>Standish M. Fleming | Director | March 25, 2002 |
| /s/ Dennis B. Gillings<br>Dennis B. Gillings | Director | March 25, 2002 |
| /s/ Henry G. Grabowski<br>Henry G. Grabowski | Director | March 25, 2002 |
| /s/ Stewart J. Hen<br>Stewart J. Hen | Director | March 25, 2002 |
| /s/ Jonathan S. Leff<br>Jonathan S. Leff | Director | March 25, 2002 |
| /s/ George McFadden | Director | March 25, 2002 |

George McFadden



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|---|---|---|
| /s/ James L. Tyree<br>---------- | Director | March 25, 2002 |
| James L. Tyree | | |