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

FORM 10-KSB

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 1998

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OF 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-22613

AVI BIOPHARMA, INC.  
(Name of small business issuer in its charter)

OREGON 93-0797222  
(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

ONE SW COLUMBIA STREET, SUITE 1105, PORTLAND, OREGON 97258  
(Address of principal executive offices) (Zip Code)

Issuer's telephone number, including area code: 503-227-0554

Securities registered under Section 12(b) of the Exchange Act: NONE  
Securities registered under Section 12(g) of the Exchange Act:  
COMMON STOCK, NO PAR VALUE  
(Title of Class)

Check whether the issuer (1) filed all reports required to be filed by  
Section 13 or 15(d) of the Exchange Act during the past 12 months (or for  
such shorter period that the Registrant was required to file such reports),  
and (2) has been subject to such filing requirements for the past 90 days:  
Yes ☒ No ☐

Check if there is no disclosure of delinquent filers in response to Item 405  
of Regulation S-B contained in this form, and no disclosure will be  
contained, to the best of registrant's knowledge, in definitive proxy or  
information statements incorporated by reference in Part III of the Form  
10-KSB or any amendment to this Form 10-KSB. ☐

Issuer's revenues for its most recent fiscal year were \$120,351. The  
aggregate market value of voting stock held by non-affiliates of the  
registrant was \$40,888,068 as of March 20, 1999, based upon the last sales  
price as reported on the Nasdaq National Market System.

The number of shares outstanding of the Registrant's Common Stock as of March  
20, 1999 was 13,351,206 shares.

Transitional Small Business Disclosure Format (check one): Yes ☐ No ☒

DOCUMENTS INCORPORATED BY REFERENCE  
The issuer has incorporated into Part III of Form 10-KSB, by reference,  
portions of its Proxy Statement for its 1999 annual meeting.

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AVI BIOPHARMA, INC.  
FORM 10-KSB INDEX

PART I

	Page
	----
Item 1. Description of Business	2
Item 2. Description of Property	20
Item 3. Legal Proceedings	20
Item 4. Submission of Matters to a Vote of Security Holders	20

PART II

Item 5. Market for Common Equity and Related Stockholder Matters	21
Item 6. Management's Discussion and Analysis or Plan of Operation	21
Item 7. Financial Statements	23
Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	23

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act	24
Item 10. Executive Compensation	24
Item 11. Security Ownership of Certain Beneficial Owners and Management	24
Item 12. Certain Relationships and Related Transactions	24
Item 13. Exhibits and Reports on Form 8-K	25
Signatures	27

PART I

ITEM 1. DESCRIPTION OF BUSINESS

GENERAL OVERVIEW

AVI BioPharma is an emerging biopharmaceutical company and a pioneer in the development of therapeutic products based upon three platform technologies:

- therapeutic cancer vaccines,
- gene-targeted drugs (antisense), and,
- drug delivery technologies.

The Company focuses its three platform technologies on two important clinical areas, cancer and cardiovascular disease. The Company is in late-stage development with Avicine, its cancer vaccine, which the Company believes may

be applicable to many cancer types. The Company also has developed Neu-Genes(R), a patented class of antisense compounds, which may prove to be useful in the treatment of a wide range of human diseases. The Company has developed a new intracellular drug delivery technology, CytoPorter(TM), which may be useful with many FDA-approved drugs as well as with drugs in development. The Company has 35 issued patents and numerous patent applications supporting its technologies. The Company is focused on developing products utilizing these technologies in large potential markets.

The Company's therapeutic cancer vaccine, Avicine, has completed five clinical trials. The Company plans three additional clinical trials, including Phase II trials in pancreatic cancer and prostate cancer, and a Phase III licensing trial in colorectal cancer. The Phase II pancreatic cancer trial will be a two-arm trial combining Avicine with gemcitabine, Lilly's state-of-the-art pancreatic cancer drug. The Phase II prostate cancer trial will test the impact of Avicine on the important prostate cancer marker PSA, prostate specific antigen. The Phase III colorectal cancer licensing trial will test Avicine versus Camptosar, the current recommended treatment for advanced colorectal cancer. All these clinical trials are expected to start in 1999.

The first application of the Company's antisense technology is designed to treat diseases involving cellular proliferation such as cancer, the cardiovascular disease called restenosis, and other proliferative disorders. The Company is currently in pre-clinical development with this multi-use compound and expects to file an Investigational New Drug Application ("IND") to begin clinical trials in 1999. The Company plans to move into preclinical development with its novel CYTOPORTER delivery engine in 1999.

The Company's long-term product development program uses its Avicine, NEU-GENE and CYTOPORTER technologies to develop drugs to treat a broad range of human diseases and combines these technologies to produce combination drugs with additional potential clinical applications. The Company has 35 issued patents and has filed patent applications covering the basic compositions of matter, methods of synthesis and therapeutic uses of its Avicine, NEU-GENE and CYTOPORTER technologies in the United States, Canada, Europe, Australia and Japan.

## DRUG DESIGN AND DEVELOPMENT

VACCINES. Avicine targets human chorionic gonadotropin (hCG), the hormone associated with fertility and fetal development. The presence of this hormone indicates pregnancy, and is responsible for stimulating fetal development. The hCG hormone is also a widely expressed tumor marker which is associated with all major histologic types including lung, colon, breast, pancreas and prostate cancers. Importantly, the expression of the hCG hormone correlates directly with the aggressiveness of the tumor; i.e. the more aggressive the tumor, the higher the hCG expression.

It is believed that the role of the hCG hormone in cancer and pregnancy is analogous. In both pregnancy and cancer, the hormone serves as a growth factor encouraging rapid cell division. Further, in both cases the hormone is required for implantation/invasion and for fostering angiogenesis, the formulation of blood vessels. Additionally, the hormone facilitates immunosuppression. The effectiveness of a vaccine to block the functions of this hormone has been demonstrated by the World Health Organization, which has tested an anti-hCG vaccine as a contraceptive method and found it to be efficacious.

Avicine has completed five clinical studies in cancer, including Phase II trials in pancreatic and colorectal cancer, in which a total of 172 patients received treatment. From these studies, the Company concluded that the vaccine is a safe and essentially non-toxic therapy, which is capable of eliciting specific immune response to the targeted hormone in most patients.

Further, the patients who could mount an immune response demonstrated survival benefits, and in some cases objective anti-tumor response. Importantly, the Company believes that there were also significant quality of life benefits for recipients of the vaccine.

ANTISENSE. Most conventional drugs are designed to induce or inhibit the function of a target protein molecule with as few side effects as possible. Conventional drugs are not available for many diseases due to their low level of selectivity for the specific disease target or because they are difficult to deliver to their targets. These two issues, lack of selectivity and poor delivery, contribute to poor efficacy, unwanted side effects or high toxicity at clinical dosages. Moreover, the development of conventional drugs is usually time consuming and expensive, since thousands of compounds must be produced and analyzed to find one with an acceptable balance between efficacy and toxicity. Safe and effective therapeutics for viral and host diseases such as cancer and cardiovascular diseases have been particularly difficult to develop because these diseases use the patient's own cellular machinery and therefore provide few disease targets for therapeutic intervention that will not prove toxic to the patient.

Antisense technology has the potential to provide safe and effective treatment for a wide range of diseases, including cancer, cardiovascular, and infectious diseases. This new approach uses synthetic compounds, or polymers, designed to block the function of genetic sequences involved in the disease process. Targeting these genetic sequences provides the selectivity that is not available in conventional drug development. The antisense approach inhibits the disease mechanism at the genetic level. The Company has completed preclinical studies with its novel antisense compounds and expects to enter Phase I/II clinical trials in 1999 for two disease indications.

### 3

INTRACELLULAR DRUG DELIVERY. Many drugs must cross tissue and cellular barriers to reach their therapeutic targets inside cells. Drugs of this type must move from the aqueous environment in blood across the lipid cell membrane and into the interior of cells. Therefore, these drugs must achieve solubility in both water and lipids. Since few compounds have these solubility characteristics, many drug candidates are a compromise between inherent solubility and effective delivery. This trade-off greatly reduces efficacy and may significantly heighten toxicity of many drug candidates as well as many FDA-approved drugs. The Company's CYTOPORTER technology specifically addresses this drug delivery challenge.

Overall, the Company has three distinct technologies designed to address these critical issues in drug development. The Company's Avicine therapeutic cancer vaccine utilizes an active immunization approach to stimulate an immune response to an existing cancer. The unique nature of the hCG vaccine target distinguishes this vaccine approach from other cancer vaccines in development. The Company's NEU-GENE antisense technology addresses the issue of drug selectivity at the genetic level. The characteristics of the patented structure of the Company's NEU-GENE compounds distinguish its antisense technology from competing technologies. The Company's molecular engine, CYTOPORTER, is designed to transport certain drugs with poor delivery characteristics across the lipid barrier of cellular membranes into the interior of cells to reach their site of action.

## PRODUCTS

### NEAR-TERM PRODUCT DEVELOPMENT SUMMARY

The Company has completed five clinical trials with Avicine, its therapeutic cancer vaccine. As a result of these trials, the Company anticipates that it will commence three additional trials in 1999; a Phase II trial in pancreatic cancer, a Phase II trial in prostate cancer, and a Phase III licensing trial in colorectal cancer. The first application of the Company's antisense

technology is designed to treat proliferation disorders; namely, cancer and restenosis.

#### CLINICAL DEVELOPMENT PROGRAM

DRUG - - - - -	POTENTIAL USAGE - - - - -	DEVELOPMENT STATUS - - - - -
Avicine	Colorectal cancer vaccine	Phase III expected to commence in 1999
Avicine	Pancreatic cancer vaccine	Phase II expected to commence in 1999
Avicine	Prostate cancer vaccine	Phase II expected to commence in 1999
Resten-NG/R	Restenosis	IND filing expected in 1999 and Phase I expected to commence in 1999
Resten-NG/C	Cancer	IND filing expected in 1999 and Phase I expected to commence in 1999

#### VACCINES - AVICINE TECHNOLOGY

##### TECHNICAL OVERVIEW

Prominent among the newer strategies to treat cancer is the therapeutic cancer vaccine approach. The rationale employed with this approach is that active immunization against the tumor can stimulate an immune response that can be effective in fighting a pre-existing cancer.

#### 4

Target sites on tumor cells, called tumor-associated antigens (TAA), represent the key components in a cancer vaccine, and the therapeutic benefit of the vaccine hinges on the selection of these target sites. AVI BioPharma's therapeutic cancer vaccine, Avicine(TM), was designed to elicit an immune response directed against a well-characterized TAA, hCG.

Normally, hCG is secreted only during pregnancy by cells of the placenta and the fertilized egg. Cancer is the only significant exception to the normal hCG secretion process. Given this selectivity, hCG is an ideal potential target for a therapeutic cancer vaccine approach. Many different human cancers produce hCG and it is considered a biochemical marker of malignancy. Since hCG is a natural human protein, people do not mount an immune response to hCG unless actively immunized.

The mechanisms by which the immune system recognizes and attacks the hCG targets on cancer cells can be through both humoral and cellular arms of the immune response. Moreover with this particular cancer target, an additional mechanism of action can be through inhibition of the growth promoting and immunosuppressive effects of hCG itself.

The advantages of hCG as a cancer vaccine target compared to other potential targets are significant. This cancer marker is not usually found on normal cells with the exception of pregnancy. It is widely expressed on all of the major histological types of cancer, and expression correlates with tumor aggressiveness. Antibodies to hCG are believed to block the hormonal functions that hCG plays in both pregnancy and cancer, including growth promotion, invasion, angiogenesis, and immunosuppression. Therefore an immune response directed against hCG can be viewed as a two-pronged attack, directing an immune attack against the tumor and neutralizing the hormonal benefits provided by hCG.

The hCG component in Avicine is the synthetic c-terminal peptide of this hormone. The peptide is conjugated to a foreign carrier, diphtheria toxoid to enhance immunogenicity. Diphtheria toxoid was selected due to wide experience with this vaccine component in man and since most of the population worldwide are vaccinated against it. This provides for an existing immune response to this carrier in patients being vaccinated and is believed to be important in stimulating an immune response to the peptide.

## CLINICAL TRIALS OF AVICINE IN CANCER

Three Phase I studies of Avicine in patients have been completed: a Phase I safety study in 43 patients, a Phase I study in 21 patients with metastatic cancer and Phase Ib study in 23 patients with metastatic cancer. Overall, these studies suggested that Avicine was safe and essentially non-toxic. Moreover, the vaccine was effective in stimulating an immune response to hCG in that most patients make antibodies to hCG post vaccination. Apparent survival benefits and some objective tumor responses were noted.

The Company has conducted a pilot Phase II study in 10 patients with advanced pancreatic cancer. Patients with advanced pancreatic cancer are currently treated with 5-FU or gemcitabine, (Gemzar(R) Lilly) and have a median survival of approximately 18 weeks and 25 weeks respectively. In the 10 advanced pancreatic patients treated with Avicine, the median survival was approximately 33 weeks. Although the Company believes these results to be encouraging, the Company hesitates to draw conclusions from such a small study other than to use these results to design additional trials.

## 5

Two additional trials have been designed and are slated to be initiated in 1999. A Phase II study in patients with advanced pancreatic cancer in which 50 patients will be randomized to two treatment arms: Avicine alone or Avicine with Gemzar. Our previous studies have shown that it takes at least 6-8 weeks to mount an immune response to hCG. During that period, patients receiving Avicine alone continue to progress. Combination therapy may be of additional benefit in that cytotoxic drug therapy may provide patients with some benefit in arresting tumor progression before an immune response develops to hCG. In this manner combination therapy of this type may provide a synergistic effect that may exceed either modality alone.

An additional Phase II combination trial has also been planned in patients with advanced pancreatic cancer. In this case, another drug, RFS-2000, currently in phase III clinical development by SuperGen Inc., will be administered with Avicine in 24 patients with advanced pancreatic cancer. RFS-2000 is a less-toxic topo-isomerase I inhibitor with promising Phase II studies reported to date.

## MULTICENTER PHASE II STUDY IN PATIENTS WITH COLORECTAL CANCER

A Phase II study of Avicine in 77 patients with advanced colorectal cancer has been completed. The primary objective of this trial was to determine whether administrations of the vaccine at two dosage schedules would induce immune responses in patients with metastatic colorectal cancer. The secondary objective of the trial was to measure safety and efficacy in these patients.

Overall, 51 of the 77 patients responded to the vaccine by producing antibodies to hCG. The patients that were antibody responders had a median survival of 42 weeks. Patients that did not respond immunologically had a median survival of just 17 weeks.

One may assume that in order to benefit from vaccine therapy for cancer, a patient must survive long enough to receive the full course of vaccination. In the group of 40 patients that fit this criterion, median survival was 46 weeks. Further analysis of these patients, showed a median survival of 58 weeks in patients on one arm of the protocol.

Overall these clinical data suggest that the patients that received Avicine and responded immunologically had improved median survival compared to patient populations treated with chemotherapeutic drugs. Avicine was found to be safe and did not exhibit toxicity associated with cytotoxic drug regimes. Based on these data, AVI BioPharma plans to initiate a Phase III licensing trial in 300 patients with advanced colorectal cancer in 1999.

TECHNICAL OVERVIEW

GENETIC STRUCTURE AND FUNCTION. All life forms contain genetic information in molecules called DNA and RNA, which comprise the operating instructions for life processes. The specific instructions are called genes, which are long chains or strands of duplex DNA composed of the four genetic bases: adenine, cytosine, guanine and thymine, represented by the letters, A, C, G, and T, respectively. The molecular structures of these letters are complementary, such that A can pair with T, and C can pair with G. Consequently, each genetic strand has the unique ability to bind specifically to a complementary strand and thereby form a duplex.

6

The information encoded in the DNA by its sequence of genetic letters is used to make proteins. To accomplish this, one strand (called the template strand) of the duplex DNA is copied to make a new complementary strand, referred to as messenger RNA. This messenger RNA is referred to as the sense strand because it carries the information used to assemble a specific protein. An antisense compound is a synthetic strand of bases in a sequence complementary to a small portion of the messenger RNA. Antisense compounds pair with their complementary messenger RNA sense strand to form a duplex, preventing the decoding of message and resultant protein assembly.

GENE-TARGETED THERAPEUTICS. Most human diseases arise from the function or dysfunction of genes within the body, either those of pathogens, such as viruses, or of one's own genes. New techniques in molecular biology have led to the identification of the genes associated with most of the major human diseases and to the determination of the sequence of their genetic letters. Using modern methods of chemical synthesis, an antisense compound can be prepared that is complementary to a target sequence in a pathogen or pathogenic process. When this complementary antisense compound binds tightly to the disease-causing sequence, the synthesis of a selected protein is inhibited, and thus the pathogen or pathogenic process is disabled.

Antisense compounds are composed of repeating structures or subunits that are linked together forming a polymer, referred to as the antisense backbone. Each subunit carries a genetic letter (A, C, G, or T) that pairs with its corresponding letter in the genetic target. Although the genetic letters are a feature common to all antisense compounds, the structure of the subunits and the linkage groups that string them together may differ greatly. These differences in the subunits and the linkages define the different types of antisense backbones and their corresponding physical and biological properties. The Company is distinguished from all other antisense companies by the characteristics of its patented antisense backbone. The subunits, which carry the genetic letters on the Company's backbone, are synthetic products rather than modified natural materials. In addition, the linkages used to string the subunits together in the Company's backbone carry no charge. The Company believes these differences will provide pharmaceutical advantages that are critical for antisense drug development to meet the challenges of broad clinical utility.

FIRST-GENERATION COMPOUNDS. The first gene-inactivating compounds had backbones composed of natural genetic materials and linkages. Development of these compounds began in the late 1960s. As work continued in this new field, it became increasingly clear that there were significant problems with these structures. These natural compounds were degraded or broken down by enzymes in the blood and within cells and had difficulty crossing cellular membranes to enter the cells that contained their genetic target.

SECOND-GENERATION COMPOUNDS. To overcome these problems of degradation and permeability, several research groups developed modified backbones in the

late 1970s, which were designed to resist degradation by enzymes and to enter tissues and cells more efficiently. The most common of these types, the phosphorothioate backbones used by ISIS Pharmaceuticals, Inex, Hybridon, and others use natural DNA subunits linked together by a sulfur-containing, charged linkage. The Company was also extensively involved in developing second-generation backbones through the mid-1980s. After extensive investigation, however, the Company concluded that even after optimization, these second-generation compounds might lack the pharmaceutical properties desirable for broad clinical utility. For this reason, the Company abandoned development of second-generation backbones in the mid-1980s and started development of third-generation backbones designed to address these drawbacks. Today, in spite of extensive progress in the field, the Company believes that there remain serious limitations to second-generation compounds

due to problems with the stability, specificity, cost effectiveness, and delivery of these compounds.

NEU-GENE THIRD-GENERATION TECHNOLOGY. By the mid-1980s, the limitations of the second-generation compounds led the Company to pursue the development of antisense technology with improved pharmaceutical properties, which could be produced and purified in a cost-effective manner. This effort culminated in the Company's development of a new class of compounds having a backbone of synthetic subunits carrying each genetic letter, with each subunit linked together by a patented uncharged linkage group. The synthetic subunits and linkages are not found in nature, but rather were designed and synthesized to meet specific pharmaceutical parameters. These patented third-generation agents, known as NEU-GENE compounds, display advantageous pharmaceutical properties (stability, neutral charge, high binding affinity and specificity). Moreover, they are made from less expensive, more abundant starting materials, and the Company believes that they will cost significantly less to produce than second-generation compounds.

The Company and others have shown in cell culture, animal and pre-clinical studies that NEU-GENE compounds inhibit targeted genetic sequences. With these scientific benchmarks in place, the Company's objective is to develop its third-generation antisense compounds into effective and affordable therapeutics for life-threatening diseases.

PHARMACEUTICAL PROPERTIES OF ANTISENSE COMPOUNDS. The Company's core technology differentiates it from others developing gene-inactivating compounds. The Company believes its principal competitive advantage in the antisense area is the chemical structure of the NEU-GENE backbone, which was developed to address all of the above parameters.

STABILITY. Biological stability is principally determined by the degree of resistance to enzymatic degradation. The Company has conducted studies indicating that NEU-GENE agents are stable to a broad range of degradative enzymes and are stable in biological tissues.

EFFICACY, POTENCY, AND SPECIFICITY. These parameters refer to the efficiency with which the antisense compounds block selected protein production. In a direct comparison with second-generation compounds, the Company's NEU-GENE compounds exhibited substantially greater efficacy, potency, and specificity in animal and preclinical studies than competing technologies.

COST EFFECTIVENESS. The Company believes that the total cost of production of commercial quantities of NEU-GENES will be significantly less than that of gene-inactivating compounds prepared from natural or modified subunits by competitors.

DELIVERY. To reach their targets, antisense compounds must cross tissue and cellular barriers, including cellular and nuclear membranes. Preliminary research in animal and preclinical studies indicates that the Company's



antisense compounds are effective in reaching and inhibiting their targets inside of cells.

#### NEAR-TERM ANTISENSE PRODUCT DEVELOPMENT B CANCER AND RESTENOSIS

The first application of the Company's antisense technology is designed to treat proliferation disorders including cancer and restenosis, a cardiovascular disease. The Company's NEU-GENE target for proliferative diseases is a transcription factor, the oncogene named c-myc. The Company believes that this target is applicable to a range of proliferative diseases

8

including many types of cancer, certain cardiovascular and inflammatory diseases, and some non-malignant proliferative disorders such as psoriasis.

9

Cancer is the second leading cause of death in the United States with an incidence of 1,500 deaths a day. There are approximately 8.5 million Americans living with a history of cancer and 500,000 new cases diagnosed annually. Cancer is a variety of different diseases with lung, prostate, breast and colorectal cancer the four most common types which account for over 50% of all newly diagnosed cancers. The market for drugs to treat each of these cancer types is estimated to be in excess of \$1 billion annually. Osteogenic sarcoma, a form of bone cancer, has been selected for the Company's initial clinical trial because it provides an ideal study setting to determine clinical efficacy and because the Company believes that clinical results in that setting would be applicable to the four major cancer types.

The Company has selected restenosis as its first cardiovascular antisense opportunity. When a patient has a blocked coronary artery, a procedure called balloon angioplasty is frequently used to remove the blockage. In this procedure, a balloon catheter is inserted in the artery up to the blockage and the balloon is inflated to expand the artery channel. During this process, vascular cells, including smooth muscle cells, which underlie the blockage, may be damaged. This process may result in rapid cell division leading to closure of the artery a second time. Restenosis occurs in approximately 30% - 40% of these procedures when stents are not placed and cannot be predicted from patient to patient. Even when stents are placed, the incidence of restenosis is significant. The precise mechanisms which cause this reaction are not known. However, scientific evidence suggests that, if the smooth muscle cells can be prevented from dividing for a period of time until the integrity of the artery is reestablished, restenosis could be prevented in a significant number of cases. Although there are a few new clinical approaches that attempt to prevent restenosis, none is very effective and all have significant risks associated with them. There are approximately 500,000 balloon angioplasties done in the U.S. each year with a market estimated at more than \$1 billion annually.

The Company has finished preclinical development with Resten-NG and expects to file an IND and initiate Phase I/II clinical trials in 1999.

#### LONG-TERM NEU-GENE DEVELOPMENT PROGRAM

The following table summarizes the Company's broader drug development program. These programs utilize the Company's NEU-GENE antisense technology and CYTOPORTER drug delivery technology. In addition, the Company anticipates combining its NEU-GENE antisense technology with its CYTOPORTER drug delivery technology to produce combination drugs. For each indication, NEU-GENES have been designed to target the disease process at the genetic level. The Company has designed CYTOPORTER to deliver drugs to their intracellular site of

action. Although NEU-GENES may display clinical efficacy on their own, the Company believes that broad use of NEU-GENES and other antisense compounds may require a drug delivery strategy.

All of the development programs listed below are in the research or lead compound stage. Disease targets have been identified and NEU-GENE compounds have been produced and tested in laboratory and/or animal models. In some cases, lead compounds have been produced which are undergoing optimization prior to pre-clinical development. The Company believes that several of these compounds may move into pre-clinical development in the next two years.

10

#### NEU-GENE Antisense Development Program

Antisense Target -----	Clinical Indication -----
C-myc	cancer cardiovascular restenosis psoriasis chronic graft rejection
Telomerase	cancer
BCL2	cancer
Bcr/abl	leukemia
NOS	cancer psoriasis chronic graft rejection
TNF alpha	rheumatoid arthritis septic shock asthma psoriasis
NF kappa B	Crohn's Disease colitis chronic inflammation
ICAM-1	arthritis psoriasis chronic graft rejection inflammatory bowel disease
Hepatitis C virus	hepatitis liver cancer
Cytomegalovirus	retinitis restenosis

C-MYC. C-myc is an oncogene that is involved in the initiation of cell division at the genetic level and is therefore referred to as a transcription factor. Inhibition of this factor blocks transcription and prevents or retards cell division. NEU-GENE antisense compounds directed against c-myc have been shown to block cell division in model systems and preclinical trials for cardiovascular restenosis and cancer. NEU-GENE compounds against c-myc are potentially applicable for the treatment of other proliferation disorders such as psoriasis and chronic graft rejection.

TELOMERASE. Telomerase is an enzyme found in cancer cells but rarely in normal cells and the Company believes that inhibiting it may provide a broad general approach to treat most cancers. There are approximately one million new cases of cancer of all types reported in the United States annually. This

leads to about 500,000 deaths in the United States attributed to cancer each year, making it the country's second leading cause of death. The Company has developed NEU-GENE compounds that block telomerase activity in model systems in the laboratory.

**BCL2.** BCL2 is a proto-oncogene that acts as a major inhibitor of senescence of cancer cells. The protein produced by this gene contributes to the progression of cancer by conveying both a survival advantage to the malignant cells over normal cells and a resistance to radiation and chemotherapy. NEU-GENE the BCL-2 gene are designed to block production of this protein in prostate, breast and a broad range of other cancers.

**BCR/ABL.** Certain types of leukemia (CML) are characterized by a genetic abnormality in which two genes referred to as BCR and ABL become linked to form a hybrid BCR/ABL gene. This gene is only found in certain cancer cells and is involved in the malignant process. NEU-GENE therapy directed at the BCR/ABL hybrid gene has the potential to provide a unique treatment for this type of leukemia.

**NITRIC OXIDE SYNTHETASE (NOS).** The NOS enzymes are involved in the transmission of signals across cellular membranes that results in cellular proliferation. Initial studies with NEU-GENES designed to block the NOS signaling pathway indicate this strategy may be useful in the prevention of cellular proliferation in a wide variety of proliferative diseases.

**TNF ALPHA.** TNF alpha has been implicated as a significant factor in psoriasis, arthritis, asthma, and other inflammatory disorders. Psoriasis is a serious chronic, recurring skin disease that involves proliferation of keratinocytes within the epidermal layer of the skin. Approximately six million individuals in the United States are afflicted by psoriasis and approximately 200,000 new cases are diagnosed annually. Current psoriasis therapies are varied but offer limited results. The Company has demonstrated that its NEU-GENE compounds are effective in inhibiting TNF alpha in laboratory and animal models of inflammation.

**NUCLEAR FACTOR KAPPA B (NF(kappa)B).** NF(kappa)B is a protein complex involved in the regulation of certain extracellular proteins at the genetic level. These matrix proteins are an essential component in the cellular adhesion process of cells that mediate immune and inflammatory responses. NEU-GENE inhibition of NF(kappa)B is potentially useful in the management of certain inflammatory diseases such as Crohn's disease, colitis, and chronic inflammation.

**ICAM-1.** ICAM-1 facilitates the migration of immune cells involved in both acute and chronic inflammation. Over-production of ICAM-1 is specifically implicated in a wide variety of inflammatory disorders, such as rheumatoid arthritis, asthma, psoriasis, organ transplant rejection, and inflammatory bowel disease. The Company has targeted NEU-GENES against the adhesion molecule ICAM-1 and is testing these compounds in models of inflammation.

**HEPATITIS C VIRUS ("HCV").** The Company has initiated a program to produce and evaluate NEU-GENE compounds directed at HCV targets. HCV is a major health problem in many parts of the world, including the United States where there are approximately 150,000 new infections each year (about 40% of all acute hepatitis cases). The mechanism of transmission may involve the exchange of blood, although the route of transmission in many cases is obscure. There are no FDA-approved vaccines or therapeutic drugs for the treatment of HCV.

**CYTOMEGALOVIRUS ("CMV").** The Company is developing NEU-GENE compounds for the treatment of CMV infections. CMV is a member of the herpes family of viruses and is the most common cause of intrauterine and congenital infections in newborns of infected mothers. CMV retinitis is a severe problem in transplant patients and patients with immunosuppression (e.g., AIDS), often leading to

blindness and pneumonitis, one of the most lethal viral syndromes. Current FDA-approved treatments for CMV retinitis suffer from

dose-limiting side effects and have been associated with the emergence of drug-resistant CMV strains.

#### DRUG DELIVERY - CYTOPORTER

Many FDA-approved drugs and drugs in do not readily make their way into cells. The Company has been developing an intracellular delivery mechanism that would allow drugs with delivery problems to be transported directly into the interior of cells. The Company has developed and has filed a patent for a molecular engine, called CYTOPORTER, to transport drugs into the interior of cells.

#### TECHNICAL OVERVIEW

The body has protective barriers that shield it from penetration by foreign agents. Two of these barriers, cell membranes and the outermost layer of the skin, are composed of lipid layers (fat-like substances). The lipid composition of these barriers prevents aqueous or water-soluble agents from the environment or in the blood from penetrating into the interior of cells and interfering with critical cellular functions. These lipid layers are the principal barriers to effective drug delivery for many drugs that have an intracellular site of action.

For optimal delivery, a drug should penetrate readily into both the aqueous compartments of the body (body fluids and the interior of cells) and into the lipid layers, which enclose those compartments. This is rarely achieved, because when lipid solubility is increased, water solubility is decreased, and vice versa. In the past, to achieve delivery, the structure of a selected drug candidate was chemically adjusted to produce a compromise in the solubility profile (e.g., less than ideal water solubility in order to achieve some level of lipid solubility). This trade-off has been successful with many drugs, but markedly less successful for many others. Currently, a significant number of FDA-approved drugs have delivery problems, and many others never make it into clinical development due to delivery problems.

CYTOPORTER DRUG DELIVERY SOLUTION. The Company believes it has developed an effective drug delivery engine, called CYTOPORTER, to facilitate the transport of polar and larger size drugs across the lipid barriers of the skin, cell membranes and endosomes into the interior of cells at a rate that is practical to achieve pharmaceutical results. Furthermore, the Company believes that its CYTOPORTER delivery engine can be chemically adjusted to accommodate a range of delivery challenges.

#### COLLABORATIVE AGREEMENTS

The Company believes that its vaccine, antisense, and drug delivery technologies are broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To exploit its core technologies as fully as possible, the Company's strategy is to enter into collaborative research agreements with major pharmaceutical companies for all cancer applications with the vaccine, and agreements directed at specific molecular targets for antisense and drug delivery. It is anticipated that antisense collaborative research agreements may provide the Company with funding for programs conducted by the Company aimed at discovering and developing antisense compounds to inhibit the production of individual molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from its collaborative research programs. The Company intends to retain manufacturing rights to its antisense products. There can be no assurance, however, it will be able to enter into collaborative

research agreements with large pharmaceutical companies on terms and conditions satisfactory to the Company.

#### MANUFACTURING

For its vaccine, the Company has identified potential Good Manufacturing Practices ("GMP") manufacturers who could meet large scale, low cost manufacturing demands for future Phase III trials and market introduction. The Company also believes that it has developed significant proprietary manufacturing techniques, which will allow large-scale, low-cost synthesis and purification of NEU-GENES. Because the Company's NEU-GENE compounds are based upon a malleable backbone chemistry, the Company believes that NEU-GENE synthesis will be more cost-effective than those of competing technologies. The Company has established sufficient manufacturing capacity to meet immediate research and development needs.

The Company currently intends to retain manufacturing rights to all products incorporating its proprietary and patented antisense technology, whether such products are sold directly by the Company or through collaborative agreements with industry partners. The Company's current production capacity is insufficient for the requirements of human clinical studies. The Company contracted with a GMP facility to produce its near term antisense therapeutic candidates for pre-clinical and clinical trial studies. There is no assurance, however, that the Company's plans will not change as a result of unforeseen contingencies.

In March 1993, the Company moved to its present laboratory facility. This facility and the laboratory procedures followed by the Company have not been formally inspected by the FDA and will have to be approved as products move from the research phase through the clinical testing phase to commercialization. The Company will be required to comply with FDA requirements for GMP in connection with human clinical trials and commercial production. See "Drug Approval Process and Other Government Regulations."

#### MARKETING STRATEGY

The Company plans to market the initial products for which it obtains regulatory approval, through marketing arrangements or other licensing arrangements with large pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products the Company develops and the Company's financial resources. The Company does not expect to establish a direct sales capability for therapeutic compounds for at least the next several years. To market products that will serve a large, geographically diverse patient population, the Company expects to enter into licensing, distribution, or partnering agreements with pharmaceutical companies that have large, established sales organizations. The timing of the Company's entry into marketing arrangements or other licensing arrangements with large pharmaceutical companies will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act, as amended, and regulations promulgated thereunder. Although the implementation of initial aspects of the Company's marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and the Company's marketing strategy therefore may not be implemented for several years. See "Drug Approval Process and Other Governmental Regulation."

## PATENTS AND PROPRIETARY RIGHTS

The proprietary nature of, and protection for, the Company's product candidates, processes and know-how are important to its business. The Company plans to prosecute and defend aggressively its patents and proprietary technology. The Company's policy is to patent the technology, inventions, and improvements that are considered important to the development of its business. The Company also relies upon trade secrets, know-how, and continuing technological innovation to develop and maintain its competitive position.

The Company owns thirty-five patents covering various facets of its current technology platforms and future developmental technologies. The Company has additional pending applications in the area of its Avicine and NEU-GENE technology, and has filed patent applications covering the basic compositions of matter, methods of synthesis, and medical uses of CYTOPORTER compounds. The Company intends to protect its proprietary technology with additional filings as appropriate.

There can be no assurance that any patents applied for will be granted or that patents held by the Company will be valid or sufficiently broad to protect the Company's technology or provide a significant competitive advantage, nor can the Company provide assurance that practice of the Company's patents or proprietary technology will not infringe third-party patents.

Although the Company believes that it has independently developed its technology and attempts to ensure that its technology does not infringe the proprietary rights of others, if infringement were alleged and proven, there can be no assurance that the Company could obtain necessary licenses on terms and conditions that would not have an adverse effect on the Company. The Company is not aware of any asserted or unasserted claims that its technology violates the proprietary rights of any person.

## DRUG APPROVAL PROCESS AND OTHER GOVERNMENT REGULATION

The production and marketing of the Company's products and its research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation. The Federal Food, Drug and Cosmetics Act, as amended, and the regulations promulgated thereunder, as well as other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of the Company's proposed products. Product development and approval within this regulatory framework take a number of years and involve the expenditure of substantial resources. In addition to obtaining FDA approval for each product, each drug manufacturing establishment must be registered with, and approved by, the FDA. Domestic manufacturing establishments are subject to regular inspections by the FDA and must comply with GMP. To supply products for use in the United States, foreign manufacturing establishments must also comply with GMP and are subject to periodic inspection by the FDA or by regulatory authorities in certain of such countries under reciprocal agreement with the FDA.

**NEW DRUG DEVELOPMENT AND APPROVAL.** The United States system of new drug approval is the most rigorous in the world. According to a February 1993 report by the Congressional Office of Technology Assessment, it cost an average of \$359 million and took an average of 15 years from discovery of a compound to bring a single new pharmaceutical product to market. Approximately one in 1,000 compounds that enter the pre-clinical testing stage eventually makes it to human testing and only one-fifth of those are

ultimately approved for commercialization. In recent years, societal and governmental pressures have created the expectation that drug discovery and development costs can be reduced without sacrificing safety, efficacy and innovation. The need to significantly improve or provide alternative strategies for successful pharmaceutical discovery, research and development remains a major health care industry challenge.

**DRUG DISCOVERY.** In the initial stages of drug discovery, before a compound reaches the laboratory, typically tens of thousands of potential compounds are randomly screened for activity in an assay assumed to be predictive of a particular disease process. This drug discovery process can take several years. Once a "screening lead" or starting point for drug development is found, isolation and structural determination are initiated. Numerous chemical modifications are made to the screening lead (called "rational synthesis") in an attempt to improve the drug properties of the lead. After a compound emerges from the above process, it is subjected to further studies on the mechanism of action and further IN VITRO animal screening. If the compound passes these evaluation points, animal toxicology is performed to begin to analyze the toxic effect of the compound, and if the results indicate acceptable toxicity findings, the compound emerges from the basic research mode and moves into the pre-clinical phase. The Company has many compounds at the drug discovery phase and three compounds that it expects to move to pre-clinical testing within 12 to 24 months.

**PRE-CLINICAL TESTING.** During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests can take up to three years or more to complete.

**INVESTIGATIONAL NEW DRUG APPLICATION.** After pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if the FDA does not reject it within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, how the chemical compound is manufactured, the method by which it is believed to work in the human body, and any toxic effects of the compound found in the animal studies. In addition, the IND must be reviewed and approved by an Institutional Review Board consisting of physicians at the hospital or clinic where the proposed studies will be conducted. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA.

**PHASE I CLINICAL TRIALS.** After an IND becomes effective, Phase I human clinical trials can begin. These studies, involving usually between 20 and 80 healthy volunteers, can take up to one year or more to complete. The studies determine a drug's safety profile, including the safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, as well as the duration of its action.

17

**PHASE II CLINICAL TRIALS.** In Phase II clinical trials, controlled studies of approximately 100 to 300 volunteer patients with the targeted disease assess the drug's effectiveness. These studies are designed primarily to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects on these patients. These studies can take up to two years or more and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted that evaluate not only the efficacy but also the safety of the drug on the patient population.

**PHASE III CLINICAL TRIALS.** This phase typically lasts up to three years or more and usually involves 1,000 to 3,000 patients with the targeted disease. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any adverse reactions that may result from long-term use of the drug.

**NEW DRUG APPLICATION ("NDA").** After the completion of all three clinical

trial phases, the data are analyzed and if the data indicate that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug that has been gathered to date, including data from the clinical trials. NDAs are often over 100,000 pages in length. The average NDA review time for new pharmaceuticals approved in 1995 was approximately 19 months.

**FAST TRACK REVIEW.** In December 1992, the FDA formalized procedures for accelerating the approval of drugs to be marketed for the treatment of certain serious diseases for which no satisfactory alternative treatment exists, such as Alzheimer's disease and AIDS. If it is demonstrated that the drug has a positive effect on survival or irreversible morbidity during Phase II clinical trials, then the FDA may approve the drug for marketing without completion of Phase III testing.

**APPROVAL.** If the FDA approves the NDA, the drug becomes available for physicians to prescribe. The Company must continue to submit periodic reports to the FDA, including descriptions of any adverse reactions reported. For certain drugs which are administered on a long-term basis, the FDA may request additional clinical studies (Phase IV) after the drug has begun to be marketed to evaluate long-term effects.

In addition to regulations enforced by the FDA, the Company also is or will be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and future federal, state or local regulations. The Company's research and development activities involve the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standard prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result, and any such liability could exceed the resources of the Company.

For marketing outside the United States, the Company or its prospective licensees will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs and devices. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

#### COMPETITION

Companies in the cancer vaccine development area include Progenics, Corixa, RIBI, Biomira, Bristol Meyers-Squibb, and E. Merck. Several companies are pursuing the development of antisense technology, including Glaxo, Boehringer Ingelheim, Hybridon, and ISIS Pharmaceuticals. All of these companies have products in development stages, and, in some cases, are in human trials with antisense compounds generally similar to the Company's NEU-GENE compounds. While the Company believes that none of these companies is likely to introduce an antisense compound into the broad commercial market in the immediate future, many pharmaceutical and biotechnology companies, including most of those listed above, have financial and technical resources greater than those currently available to the Company and have more established collaborative relationships with industry partners than does the Company. The Company believes that the combination of pharmaceutical properties of its NEU-GENE compounds for cancer and restenosis afford it competitive advantages when compared with the antisense compounds of competitors. Many companies are pursuing drug delivery technology, including Biovail, Cygnus, and Noven, among others. If the Company's antisense and drug delivery technologies attain regulatory and commercial acceptance as the basis for the commercial pharmaceutical products, it is to be expected that additional companies, including large, multinational pharmaceutical companies, will choose to compete in the Company's markets, either directly or through collaborative



arrangements.

The Company can also expect to compete with other companies exploiting alternative technologies that address the same therapeutic needs, as does the Company's technology. The biopharmaceutical market is subject to rapid technological change, and it can be expected that competing technologies will emerge and will present a competitive challenge to the Company.

#### RESEARCH AND DEVELOPMENT

The Company expensed \$6,306,860 and \$2,737,172 on research and development activities during the years ended December 31, 1998 and 1997.

#### EMPLOYEES

As of December 31, 1998, the Company had 54 employees, 20 of whom hold advanced degrees. Forty-eight employees are engaged directly in research and development activities, and six are in administration. None of the Company's employees is covered by collective bargaining agreements, and management considers relations with its employees to be good.

19

#### ITEM 2. DESCRIPTION OF PROPERTY

The Company occupies 18,400 square feet of leased laboratory and office space at 4575 S.W. Research Way, Suite 200, Corvallis, Oregon 97333. The Company's executive office is located in 2,400 square feet of leased space at One S.W. Columbia, Suite 1105, Portland, Oregon 97258. The Company believes that its facilities are suitable and adequate for its present operational requirements and that it is not dependent upon any individually leased premises.

#### ITEM 3. LEGAL PROCEEDINGS

As of March 18, 1999, there were no material, pending legal proceedings to which the Company or its subsidiaries are a party. From time to time, the Company becomes involved in ordinary, routine or regulatory legal proceedings incidental to the business of the Company.

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

No matters were submitted to a vote of the Company's shareholders during the quarter ended December 31, 1998.

20

### PART II

#### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock is quoted on the Nasdaq National Market System ("Nasdaq NMS") under the symbol "AVII." The following table sets forth the high and low sales prices as reported by Nasdaq NMS from the time of the Company's initial public offering, June 3, 1997.

Year Ended December 31, 1997

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Quarter 2 (from June 3, 1997)	\$	7.25	\$	5.75
Quarter 3		7.50		6.44

Quarter 4	9.50	6.69
Year Ended December 31, 1998		
-----		
Quarter 1	\$ 7.82	\$ 5.75
Quarter 2	8.00	5.62
Quarter 3	6.31	2.62
Quarter 4	5.19	2.50

The number of shareholders of record and approximate number of beneficial holders on March 20, 1999 was 910 and 2,556, respectively. There were no cash dividends declared or paid in fiscal years 1998 or 1997. The Company does not anticipate declaring such dividends in the foreseeable future.

There were no sales of unregistered securities by the Company during the period from June 3, 1997, the date of its initial public offering, through December 31, 1998.

#### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

##### FORWARD-LOOKING INFORMATION

The statements which are not historical facts contained in this discussion are forward looking statements that involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the Company's Securities and Exchange Commission filings.

##### OVERVIEW

From its inception in 1980, the Company has devoted its resources primarily to fund its research and development efforts. The Company has been unprofitable since inception and, other than limited interest and grant revenue, has had no material revenues from the sale of products or other sources, and does not expect material revenues for at least the next 12 months. The Company expects to continue to incur losses for the foreseeable future as it expands its research and development efforts. As of December 31, 1998, the Company's accumulated deficit was \$42,775,436.

##### RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 1997 COMPARED WITH YEAR ENDED DECEMBER 31, 1998. Operating expenses increased from \$4,019,386 in 1997 to \$27,401,395 in 1998 principally due to a one-time charge of \$19,473,154 for acquired in-process research and development reflecting the recently completed acquisition of ITC and increases in research and development staffing and increased expenses associated with outside collaborations and pre-clinical testing of the Company's technologies. In connection with the purchase price allocation for ITC, the Company estimated the fair value of the intangible assets which indicated that the majority of all of the acquired intangible assets consisted of research and development projects in process. At that time, the development of these projects had not reached technological feasibility and the technology was believed to have no alternative future use. In accordance with generally accepted accounting principles, the acquired in-process research and development has been reflected in the accompanying financial statements. The Company currently believes that the research and development efforts may result in commercially feasible products after at least 36 months and at an additional estimated cost of at least \$10 million. Additionally,

increased general and administrative costs were incurred to support the research expansion, and to broaden the Company's investor and public relations efforts due to its change in status to a public company in mid-1997. Net interest income increased from \$389,051 in 1997 to \$547,081 in 1998 due to earnings on increased cash balances, which consisted of proceeds from the initial public offerings.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations since inception primarily through equity sales totaling \$34,902,503 and grants and contract research funding of \$824,193 from various sources. The Company's cash and cash equivalents were \$8,510,020 at December 31, 1998, compared with \$17,638,936 at December 31, 1997. The decrease of \$9,128,916 was due to increases in research and development staffing and increased expenses associated with outside collaborations and pre-clinical testing of the Company's technologies and the recently completed acquisition of ITC.

The Company's future expenditures and capital requirements will depend on numerous factors, including without limitation, the progress of its research and development programs, the progress of its pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, the ability of the Company to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of its products. The Company's cash requirements are expected to continue to increase significantly each year as it expands its activities and operations. There can be no assurance, however, that the Company will ever be able to generate product revenues or achieve or sustain profitability.

The Company expects that its cash requirements over the next twelve months will be satisfied by existing cash resources.

#### YEAR 2000

The Year 2000 issue results from computer programs operating incorrectly when the calendar year changes to January 1, 2000. Computer programs that have date-sensitive software may recognize a two-digit date using "00" as calendar year 1900 rather than the year 2000. This could result in system failure or miscalculations and could cause disruptions of operations, including, among other things, a temporary inability to engage in normal business activities.

The Company has evaluated its technology and data, including imbedded non-informational technology, used in the creation and development of its products and services and in its internal operations and has identified no significant Year 2000 issues. The core business systems are compliant, or a migration path to a compliant version will be in place by the year 2000. The Company has not incurred material costs and believes that future costs associated with addressing the Year 2000 issue will have an immaterial effect on the Company's financial results.

Although the Company has inquired of certain of its significant vendors as to the status of their Year 2000 compliance initiatives, no binding assurances have been received. The Company believes that parts and services used in normal operations can be obtained from multiple sources and therefore is not overly reliant on any single vendor. Failure of telephone service providers or other monopolistic utilities could have a significant detrimental effect on the Company's operations. There can be no assurances that such third parties will successfully address their own Year 2000 issues over which the Company has no control.

ITEM 7. FINANCIAL STATEMENTS

The information required by this item begins on page F-1 of this report.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

23

PART III

ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information regarding directors and executive officers of the registrant required by this item is included in the Company's definitive proxy statement for its 1999 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

ITEM 10. EXECUTIVE COMPENSATION

The information required by this item is included in the Company's definitive proxy statement for its 1999 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is included in the Company's definitive proxy statement for its 1999 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is included in the Company's definitive proxy statement for its 1999 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

24

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

EXHIBITS

The following exhibits are filed herewith and this list is intended to constitute the exhibit index:

Exhibit No.	Description
- - - - -	- - - - -
3.1	Third Restated Articles of Incorporation of AntiVirals Inc. (1)
3.2	Bylaws of Antivirals Inc. (1)

3.3 First Amendment to Third Restated Articles of Incorporation (4)

4.1 Form of Specimen Certificate for Common Stock. (1)

4.2 Form of Warrant for Purchase of Common Stock. (1)

4.3 Form of Warrant Agreement. (1)

4.4 Form of Representative's Warrant. (1)

4.5 Form of Warrant Agreement between AntiVirals Inc. and Immuno Therapy Shareholders (3)

10.1 1992 Stock Incentive Plan. (1)

10.2 Employment Agreement with Denis R. Burger, Ph.D. dated November 4, 1996. (1)

10.3 Employment Agreement with Alan P. Timmins dated November 4, 1996. (1)

10.4 Employment Agreement with Dwight Weller, Ph.D. dated November 4, 1996. (1)

10.5 Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1992. (1)

10.6 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc. dated January 20, 1996.(1)

10.7 License and Option Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1993. (1)

10.8 Commercial Lease between Research Way Investments, Landlord, and AntiVirals Inc., Tenant, dated June 15, 1992. (1)

10.9 Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated June 17, 1992. (1)

10.10 First Amendment to Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated July 24, 1995. (1)

10.11 Employment Agreement with Patrick L. Iversen, Ph.D. dated July 14, 1997. (2)

10.12 ImmunoTherapy Corporation 1997 Stock Option Plan (3)

10.13 Form of Employment Agreement with Jeffrey Lillard (3)

10.14 Promissory Note dated June, 1998 made by the Lillard Family Trust to AntiVirals Inc. (3)

10.15 Oregon Deed of Trust Security Agreement and Fixture Filing dated June, 1998, granted by the Lillard Family Trust to Fidelity National Title Company of Oregon, as trustee, for the benefit of AntiVirals Inc. (3)

10.16 License Agreement between ImmunoTherapy Corporation and Ohio State University, dated March 12, 1996 (3)

10.17 License Agreement between ImmunoTherapy Corporation and Ohio State University, dated December 26, 1996 (3)

10.18 Amendment to License Agreement between ImmunoTherapy Corporation and Ohio State University, dated September 23, 1997 (3)

10.19 Agreement and Plan of Reorganization and Merger dated as of February 2, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)

25

10.20 First Amendment to Plan of Reorganization and Merger dated as of May 27, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)

10.21 Second Amendment to Plan of Reorganization and Merger dated as of August 4, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)

10.22 Form of Escrow Agreement among AntiVirals Inc., the Escrow Indemnitors and Jeffrey Lillard (3)

23.0 Consent of Arthur Andersen LLP

27.0 Financial Data Schedule

- (1) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form SB-2, as amended and filed with the Securities and Exchange Commission on May 29, 1997 (Commission Registration No. 333-20513).
- (2) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, and filed with the Securities and Exchange Commission on March 30, 1998.
- (3) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-4, as amended and filed with the Securities and Exchange Commission on August 7, 1998 (Commission Registration No. 333-60849).
- (4) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on September 30, 1998 (Commission Registration No. 000-22613).

#### REPORTS ON FORM 8-K

The Company did not file any Reports on Form 8-K during the quarter ended December 31, 1998.

26

#### SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 24, 1999

AVI BIOPHARMA, INC.

By: /s/ Denis R. Burger, Ph.D.

-----  
Denis R. Burger, Ph.D.  
Chairman of the Board,  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in their capacities indicated on March 24, 1999:

Signature - -----	Title -----
/s/ DENIS R. BURGER, Ph.D. - ----- Denis R. Burger, Ph.D.	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)
/s/ ALAN P. TIMMINS - ----- Alan P. Timmins	Chief Operating Officer, Chief Financial Officer and Director (Principal Financial and Accounting Officer)
/s/ PATRICK L. IVERSEN, Ph.D. - ----- Patrick L. Iversen, Ph.D.	Senior Vice President of Research and Development and Director
/s/DWIGHT D. WELLER, Ph.D. - ----- Dwight D. Weller, Ph.D.	Senior Vice President of Chemistry and Manufacturing and Director
/s/JEFFREY L. LILLARD - ----- Jeffrey L. Lillard	Vice President and Director
/s/ NICK BUNICK - ----- Nick Bunick	Director
/s/ BRUCE L.A. CARTER, Ph.D. - ----- Bruce L.A. Carter, Ph.D.	Director
/s/ JAMES B. HICKS, Ph.D. - ----- James B. Hicks, Ph.D.	Director
/s/ JOSEPH RUBINFELD, Ph.D. - ----- Joseph Rubinfeld, Ph.D.	Director

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Board of Directors and Shareholders of  
AVI BIOPHARMA, INC.

We have audited the accompanying balance sheets of AVI BIOPHARMA, INC. (an Oregon corporation in the development stage) as of December 31, 1998 and 1997, and the related statements of operations, shareholders' equity and cash

flows for the years ended December 31, 1998 and 1997 and for the period from inception (July 22, 1980) to December 31, 1998. 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 in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BIOPHARMA, INC. as of December 31, 1998 and 1997, and the results of its operations and its cash flows for the years ended December 31, 1998 and 1997 and for the period from inception (July 22, 1980) to December 31, 1998, in conformity with generally accepted accounting principles.

ARTHUR ANDERSEN LLP

Portland, Oregon  
January 27, 1999

F-1

AVI BIOPHARMA, INC.  
(A Development Stage Company)  
BALANCE SHEETS

	December 31,	
	1998	1997
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,510,020	\$ 17,638,936
Other current assets	509,428	19,042
Total Current Assets	9,019,448	17,657,978
Property and Equipment, net of accumulated depreciation and amortization of \$2,386,310 and \$2,262,755	411,828	438,820
Patent Costs, net of accumulated amortization of \$305,310 and \$218,773	730,960	553,063
Deferred Acquisition Costs	-	102,506
Other Assets	29,847	29,847
Total Assets	\$ 10,192,083	\$ 18,782,214
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 891,928	\$ 219,083
Accrued liabilities	294,471	245,369
Total Current Liabilities	1,186,399	464,452
Shareholders' Equity:		
Preferred Stock, \$.0001 par value, 2,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$.0001 par value, 50,000,000 shares authorized; 13,346,166 and 11,125,617 issued and outstanding	1,335	1,113
Additional paid-in capital	51,779,785	34,358,122
Deficit accumulated during the development stage	(42,775,436)	(16,041,473)



Total Shareholders' Equity	9,005,684	18,317,762
Total Liabilities and Shareholders' Equity	\$ 10,192,083	\$ 18,782,214

The accompanying notes are an integral part of these balance sheets.

F-2

AVI BIOPHARMA, INC.  
(A Development Stage Company)  
STATEMENTS OF OPERATIONS

	Year ended December 31, 1998	1997	July 22, 1980 (Inception) to December 31, 1998
Revenues, from grants and research contracts	\$ 120,351	\$ 14,345	\$ 824,193
Operating expenses:			
Research and development	6,306,860	2,737,172	18,055,606
General and administrative	1,621,381	1,282,214	7,453,177
Acquired in-process research and development	19,473,154	-	19,473,154
	27,401,395	4,019,386	44,981,937
Other Income:			
Interest income, net	547,081	389,051	1,285,558
Realized gain on sale of short-term investments	-	-	96,750
	547,081	389,051	1,382,308
Net loss	\$ (26,733,963)	\$ (3,615,990)	\$ (42,775,436)
Net loss per share - basic and diluted	\$ (2.27)	\$ (0.36)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	11,801,453	10,078,962	

The accompanying notes are an integral part of these statements.

F-3

AVI BIOPHARMA, INC.  
(A Development Stage Company)  
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock Shares	Amount	Additional Paid-In Capital	Unrealized Gain on Available- For-Sale Securities	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT JULY 22, 1980 (Inception)	-	-	\$ -	\$ -	\$ -	\$ -	\$ -
No activity	-	-	-	-	-	-	-
BALANCE AT OCTOBER 31, 1980	-	-	-	-	-	-	-
Issuance of partnership units and common stock in October 1981 for equipment and supplies valued at \$3,500 and technology	1,000	1,666,667	167	3,333	-	-	3,500
Issuance of partnership units and common stock for cash, \$500 per unit	150	250,000	25	75,055	-	-	75,080
Issuance of partnership units for consulting services, \$500 per unit	10	-	-	5,000	-	-	5,000
Issuance of common stock in connection with financing agreement	-	33,333	3	7	-	-	10

Net loss	-	-	-	-	-	(9,224)	(9,224)
BALANCE AT OCTOBER 31, 1981	1,160	1,950,000	195	83,395	-	(9,224)	74,366
Issuance of common stock for consulting services	-	54,600	5	11	-	-	16
Net loss	-	-	-	-	-	(57,962)	(57,962)
BALANCE AT OCTOBER 31, 1982	1,160	2,004,600	200	83,406	-	(67,186)	16,420
Issuance of partnership units and common stock for cash, \$550 per unit	60	100,000	10	33,020	-	-	33,030
Issuance of common stock for consulting services	-	21,733	2	5	-	-	7
Net loss	-	-	-	-	-	(27,475)	(27,475)
BALANCE AT OCTOBER 31, 1983	1,220	2,126,333	212	116,431	-	(94,661)	21,982
Issuance of partnership units and common stock for cash, \$600 per unit	10	16,667	2	6,003	-	-	6,005
Issuance of partnership units and common stock for consulting services and \$1,000 cash, \$550 to \$600 per unit	20	16,667	2	11,503	-	-	11,505
Issuance of common stock for consulting services	-	2,533	-	1	-	-	1
Issuance of common stock for donation to charitable organizations	-	100,000	10	20	-	-	30
Net loss	-	-	-	-	-	(21,463)	(21,463)
BALANCE AT OCTOBER 31, 1984	1,250	2,262,200	226	133,958	-	(116,124)	18,060
Issuance of partnership units and common stock in December 1984 for technology	1,000	166,667	16	(16)	-	-	-
Issuance of partnership units and common stock for cash, \$50 to \$100 per unit	460	78,333	8	23,515	-	-	23,523
Issuance of partnership units for cash, \$50 to \$550 per unit	140	-	-	17,000	-	-	17,000
Issuance of common stock for consulting services	-	6,733	1	1	-	-	2
Net loss	-	-	-	-	-	(8,469)	(8,469)
BALANCE AT OCTOBER 31, 1985	2,850	2,513,933	251	174,458	-	(124,593)	50,116
Issuance of partnership units and common stock for cash, \$50 to \$500 per unit	90	105,000	11	31,521	-	-	31,532
Issuance of common stock for consulting services	-	8,500	1	1	-	-	2
Net loss	-	-	-	-	-	(32,353)	(32,353)
BALANCE AT OCTOBER 31, 1986	2,940	2,627,433	263	205,980	-	(156,946)	49,297

The accompanying notes are an integral part of these statements.

F-4

AVI BIOPHARMA, INC.  
(A Development Stage Company)  
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock		Additional Paid-In Capital	Unrealized Gain on Available- For-Sale Securities	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
		Shares	Amount				
BALANCE AT OCTOBER 31, 1986	2,940	2,627,433	\$ 263	\$ 205,980	\$ -	\$ (156,946)	\$ 49,297
Issuance of partnership units and common stock for cash, \$500 per unit	20	33,333	3	10,007	-	-	10,010
Issuance of partnership units and warrants to purchase 400,000 shares of common stock for cash, \$500 to \$2,500 per unit	80	-	-	100,000	-	-	100,000
Issuance of common stock for consulting services	-	28,533	3	6	-	-	9
Net loss	-	-	-	-	-	(71,616)	(71,616)
BALANCE AT OCTOBER 31, 1987	3,040	2,689,299	269	315,993	-	(228,562)	87,700
Issuance of partnership units and common stock for cash, \$500 per unit	100	166,667	17	50,033	-	-	50,050
Issuance of partnership units and common stock for cash, \$1,250 per unit	20	33,333	3	25,007	-	-	25,010
Issuance of partnership units for cash, \$50 per unit	20	-	-	1,000	-	-	1,000
Issuance of partnership units and warrants to purchase 400,000 shares of common stock for cash, \$1,250 per unit	80	-	-	100,000	-	-	100,000
Compensation expense related to issuance of warrants for partnership units	-	-	-	10,000	-	-	10,000
Issuance of common stock for consulting services and employee compensation	-	47,014	5	9	-	-	14
Net loss	-	-	-	-	-	(266,194)	(266,194)
BALANCE AT OCTOBER 31, 1988	3,260	2,936,313	294	502,042	-	(494,756)	7,580
Exercise of warrants for common stock	-	141,667	14	28	-	-	42
Issuance of partnership units and common stock for cash, \$1,250 per unit	10	16,667	1	12,504	-	-	12,505
Issuance of partnership units and warrants to purchase 800,000 shares of common stock for cash, \$1,250 per unit	160	-	-	200,000	-	-	200,000
Issuance of common stock for consulting services and employee compensation	-	17,733	2	4	-	-	6
Compensation expense related to issuance of warrants for partnership units	-	-	-	2,500	-	-	2,500
Net loss	-	-	-	-	-	(243,926)	(243,926)

BALANCE AT OCTOBER 31, 1989	3,430	3,112,380	311	717,078	-	(738,682)	(21,293)
Exercise of warrants for common stock	-	33,333	3	7	-	-	10
Issuance of partnership units and common stock for cash, \$1,250 per unit	74	123,334	12	92,525	-	-	92,537
Issuance of partnership unit for cash, \$5,000 per unit	1	-	-	5,000	-	-	5,000
Issuance of common stock for cash, \$4.56 per share	-	1,100	-	5,000	-	-	5,000
Issuance of partnership units and warrants to purchase 200,000 shares of common stock for cash, \$1,250 per unit	40	-	-	50,000	-	-	50,000
Issuance of common stock for consulting services and employee compensation	-	11,400	2	51,678	-	-	51,680
Compensation expense related to issuance of warrants for partnership units	-	-	-	40,000	-	-	40,000
Exercise of warrant for partnership units	10	-	-	12,500	-	-	12,500
Net loss	-	-	-	-	-	(351,772)	(351,772)
BALANCE AT OCTOBER 31, 1990	3,555	3,281,547	328	973,788	-	(1,090,454)	(116,338)

The accompanying notes are an integral part of these statements.

F-5

AVI BIOPHARMA INC.  
(A Development Stage Company)  
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock Shares	Amount	Additional Paid-In Capital	Unrealized Gain on Available- For-Sale Securities	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT OCTOBER 31, 1990	3,555	3,281,547	\$ 328	\$ 973,788	\$ -	\$ (1,090,454)	\$ (116,338)
Issuance of partnership units for cash, \$5,000 per unit	23.5	-	-	117,500	-	-	117,500
Exercise of warrants for partnership units and common stock	1	1,100	-	1,250	-	-	1,250
Issuance of common stock for cash, \$4.56 per share	-	24,750	3	112,505	-	-	112,508
Compensation expense related to issuance of warrants for common stock	-	-	-	1,520	-	-	1,520
Issuance of common stock for consulting services, \$4.56 per share	-	1,657	-	7,547	-	-	7,547
Common stock subject to rescission	-	(7,127)	(1)	(32,499)	-	-	(32,500)
Net loss	-	-	-	-	-	(274,844)	(274,844)
BALANCE AT OCTOBER 31, 1991	3,579.5	3,301,927	33	1,181,611	-	(1,365,298)	(183,357)
Issuance of partnership units for cash, \$5,000 per unit	15.5	-	-	77,500	-	-	77,500
Issuance of common stock for cash, \$4.56 per share	-	17,050	2	77,498	-	-	77,500
Compensation expense related to issuance of warrants for common stock	-	-	-	7,500	-	-	7,500
Common stock subject to rescission	-	(32,486)	(3)	(148,135)	-	-	(148,138)
Net loss	-	-	-	-	-	(91,588)	(91,588)
BALANCE AT DECEMBER 31, 1991	3,595	3,286,491	329	1,195,974	-	(1,456,886)	(260,583)
Issuance of partnership units for cash, \$5,000 per unit	30.5	-	-	152,500	-	-	152,500
Exercise of warrants for partnership units and common stock	22	2,200	-	28,750	-	-	28,750
Conversion of debt into common stock and partnership units	9	9,634	1	87,859	-	-	87,860
Issuance of common stock for cash, \$4.56 per share	-	868,906	87	3,954,625	-	-	3,954,712
Issuance of common stock for consulting services, \$4.56 per share	-	22,872	2	104,167	-	-	104,169
Compensation expense related to issuance of warrants for common stock and partnership units	-	-	-	262,833	-	-	262,833
Common stock subject to rescission	-	(410,099)	(41)	(1,870,008)	-	-	(1,870,049)
Net loss	-	-	-	-	-	(1,731,138)	(1,731,138)
BALANCE AT DECEMBER 31, 1992	3,656.5	3,780,004	378	3,916,700	-	(3,188,024)	729,054
Exercise of warrants for partnership units	9	-	-	4,500	-	-	4,500
Issuance of common stock in exchange for partnership units	(1,809.5)	1,632,950	163	(163)	-	-	-
Withdrawal of partnership net assets upon conveyance of technology	(1,856)	-	-	(176,642)	-	-	(176,642)
Issuance of common stock for cash and short-term investments, \$4.95 per share	-	507,084	50	2,510,014	-	-	2,510,064
Exercise of warrants for common stock	-	3,844	1	9,999	-	-	10,000
Common stock subject to rescission	-	(808,902)	(81)	(901,119)	-	-	(901,200)
Net loss	-	-	-	-	-	(2,346,939)	(2,346,939)
BALANCE AT DECEMBER 31, 1993	-	5,114,980	511	5,363,289	-	(5,534,963)	(171,163)
Issuance of common stock for cash, \$4.95 per share	-	565,216	57	2,797,761	-	-	2,797,818
Exercise of warrants for common stock	-	24,667	2	122,098	-	-	122,100
Issuance of common stock for consulting	-	-	-	-	-	-	-

services, \$4.95 per share	-	151	-	749	-	-	749
Unrealized gain on available-for-sale securities	-	-	-	-	61,000	-	61,000
Common stock subject to rescission	-	(34,359)	(3)	(170,075)	-	-	(170,078)
Net loss	-	-	-	-	-	(2,246,272)	(2,246,272)
BALANCE AT DECEMBER 31, 1994	-	5,670,655	567	8,113,822	61,000	(7,781,235)	394,154

F-6

AVI BIOPHARMA INC.  
(A Development Stage Company)  
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock Shares	Amount	Additional Paid-In Capital	Unrealized Gain on Available- For-Sale Securities	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT DECEMBER 31, 1994	-	5,670,655	\$ 567	\$ 8,113,822	\$ 61,000	\$ (7,781,235)	\$ 394,154
Issuance of common stock for cash, \$6.00 per share	-	146,183	15	862,674	-	-	862,689
Compensation expense related to issuance of warrants for common stock	-	-	-	213,000	-	-	213,000
Unrealized gain on available-for-sale securities	-	-	-	-	35,750	-	35,750
Net loss	-	-	-	-	-	(2,556,886)	(2,556,886)
BALANCE AT DECEMBER 31, 1995	-	5,816,838	582	9,189,496	96,750	(10,338,121)	(1,051,293)
Exercise of warrants for common stock	-	957,452	96	(96)	-	-	-
Issuance of common stock for cash, \$6.00 per share	-	712,500	71	4,031,461	-	-	4,031,532
Liquidation of available-for-sale securities	-	-	-	-	(96,750)	-	(96,750)
Net loss	-	-	-	-	-	(2,087,362)	(2,087,362)
BALANCE AT DECEMBER 31, 1996	-	7,486,790	749	13,220,861	-	(12,425,483)	796,127
Exercise of warrants for common stock	-	50,000	5	5,010	-	-	5,015
Exercise of options for common stock	-	59,903	6	281,804	-	-	281,810
Issuance of common stock and warrants for cash, \$9.00 per unit, net of offering costs	-	2,300,000	230	18,017,400	-	-	18,017,630
Reclassified upon completion of rescission offering	-	1,228,924	123	2,833,047	-	-	2,833,170
Net loss	-	-	-	-	-	(3,615,990)	(3,615,990)
BALANCE AT DECEMBER 31, 1997	-	11,125,617	1,113	34,358,122	-	(16,041,473)	18,317,762
Exercise of warrants for common stock	-	34,567	3	17,922	-	-	17,925
Exercise of options for common stock	-	35,990	4	166,944	-	-	166,948
Issuance of common stock and warrants for the acquisition of ImmunoTherapy Corporation	-	2,132,592	213	17,167,199	-	-	17,167,412
Issuance of common stock for consulting services, \$4.00 per share	-	17,400	2	69,598	-	-	69,600
Net loss	-	-	-	-	-	(26,733,963)	(26,733,963)
BALANCE AT DECEMBER 31, 1998	-	13,346,166	\$ 1,335	\$51,779,785	\$ -	\$ (42,775,436)	\$ 9,005,684

F-7

AVI BIOPHARMA INC.  
(A Development Stage Company)  
STATEMENTS OF CASH FLOWS

	Year ended December 31,		For the Period July 22, 1980 (Inception) to December 31, 1998
	1998	1997	
Cash flows from operating activities:			
Net loss	\$ (26,733,963)	\$ (3,615,990)	\$ (42,775,436)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	223,186	467,250	2,740,293
Realized gain on sale of short-term investments - available for sale	-	-	(96,750)
Compensation expense on issuance of common stock and partnership units	69,600	-	251,992
Compensation expense on issuance of options and warrants to purchase common stock or partnership units	-	-	562,353
Conversion of interest accrued to common stock	-	-	7,860
Acquired in-process research and development	19,473,154	-	19,473,154
(Increase) decrease in:			
Other current assets	(490,386)	9,213	(509,428)
Other assets	-	-	(29,847)
Net increase in accounts payable and accrued liabilities	721,947	133,645	1,186,399

Net cash used in operating activities	(6,736,462)	(3,005,882)	(19,189,410)
Cash flows from investing activities:			
Proceeds from sale or redemption of short-term investments	-	30,000	247,750
Purchase of property and equipment	(109,657)	(323,798)	(2,846,811)
Patent costs	(264,434)	(128,877)	(1,036,270)
Acquisition costs	(2,203,236)	(102,506)	(2,305,742)
Net cash used in investing activities	(2,577,327)	(525,181)	(5,941,073)
Cash flows from financing activities:			
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options	184,873	18,447,565	34,025,940
Buyback of common stock pursuant to rescission offering	-	(288,795)	(288,795)
Withdrawal of partnership net assets	-	-	(176,642)
Issuance of convertible debt	-	-	80,000
Net cash provided by financing activities	184,873	18,158,770	33,640,503
Increase (decrease) in cash and cash equivalents	(9,128,916)	14,627,707	8,510,020
Cash and cash equivalents:			
Beginning of period	17,638,936	3,011,229	-
End of period	\$ 8,510,020	\$ 17,638,936	\$ 8,510,020

F-8

AVI BIOPHARMA, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND NATURE OF BUSINESS:

AVI BioPharma, Inc. (the Company) was incorporated in the State of Oregon on July 22, 1980. The mission of the Company is to develop and commercialize improved therapeutic products based upon antisense and drug delivery technology.

Through May 1993, the financial statements include the combined accounts of the Company and ANTI-GENE DEVELOPMENT GROUP, a limited partnership (AGDG or the Partnership) founded in 1981 and registered in the State of Oregon. Substantially all income generated and proceeds from the Partnership unit sales have been paid to the Company under the terms of research and development contracts entered into by the Partnership and the Company. Significant transactions between the Company and the Partnership have been eliminated.

In March 1993, the Company offered to all partners in the Partnership the opportunity to exchange their partnership units or warrants to purchase partnership units (unit warrants) for common stock or warrants to purchase common stock. Under the terms of the offer, which was completed May 1, 1993, each partner could elect to exchange each unit held or unit warrant held for 1,100 shares of common stock or warrants to purchase 1,100 shares of common stock of the Company, respectively. One partner exchanged 325 partnership units for warrants to purchase 357,500 shares of common stock. Total shares and warrants to purchase shares issued in the exchange offer were 1,632,950 and 381,700, respectively.

Effective May 19, 1993, the Company and the Partnership entered into a Technology Transfer Agreement wherein the Partnership conveyed all intellectual property in its control to the Company. As part of the conveyance, the Company tendered to the Partnership for liquidation all partnership units received pursuant to the exchange offer and received a 49.37 percent undivided interest in the intellectual property. The Company then purchased the remaining undivided interest in the intellectual property for rights to payments of 2 percent of gross revenues from sales of products, which would, in the absence of the Technology Transfer Agreement, infringe a valid claim under any patent transferred to the Company. The Company also granted to the Partnership a royalty-bearing license to make, use and sell

small quantities of product derived from the Intellectual Property for research purposes only.

The remaining net assets of the Partnership, \$176,642 of cash, were no longer combined with those of the Company in May 1993. Under the terms of the Technology Transfer Agreement, the Partnership ceased active sales of partnership units and income generating activities and no longer will enter into research and development contracts with the Company. The Partnership currently exists primarily for the purpose of collecting potential future payments from the Company as called for in the Technology Transfer Agreement.

Beginning in 1991, the Company changed its fiscal year from a fiscal year ending on October 31, to a calendar year. The new fiscal year was adopted prospectively.

#### F-9

The Company is in the development stage. Since its inception in 1980 through December 31, 1998, the Company has incurred losses of approximately \$43 million. Losses for 1998 include a one-time charge of \$19,473,154 for acquired in-process research and development reflecting the recently completed acquisition of ITC and expenditures related to research and development and general and administrative expenses. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company nevertheless expects to incur operating losses over the next several years. The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on its completing product development of its cancer vaccine, antisense and/or drug delivery products, obtaining regulatory approvals for such products and bringing these products to market. During the period required to develop these products, the Company will require substantial financing. There is no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. If necessary, the Company's management will curtail expenditures in an effort to conserve operating funds. The likelihood of the long-term success of the Company must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace as well as the burdensome regulatory environment in which the Company operates. There can be no assurance that the Company will ever achieve significant revenues or profitable operations.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

### 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.

### CASH AND CASH EQUIVALENTS

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

### PROPERTY AND EQUIPMENT

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally five years, using the straight-line

method. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

#### PATENT COSTS

Patent costs consist primarily of legal and filing fees incurred to file patents on proprietary technology developed by the Company. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the legal lives of the patents, generally 17 years.

F-10

#### RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred.

#### INCOME TAXES

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are recorded based on the tax effected difference between the tax bases of assets and liabilities and their carrying amount for financial reporting purposes, referred to as temporary differences, using enacted marginal income tax rates.

#### NET LOSS PER SHARE

Basic EPS is calculated using the weighted average number of common shares outstanding for the period and diluted EPS is computed using the weighted average number of common shares and dilutive common equivalent shares outstanding. Given that the Company is in a loss position, there is no difference between basic EPS and diluted EPS since the common stock equivalents would be antidilutive.

The Company's net loss for the year ended December 31, 1998 includes a one-time charge of \$19,473,154, or \$1.65 per share, for acquired in-process research and development, reflecting the recently completed acquisition of ImmunoTherapy Corporation (Note 6).

Year Ended December 31, -----	1998 -----	1997 -----
Net loss	\$ (26,733,963)	\$ (3,615,990)
Weighted average number of shares of common stock and common stock equivalents outstanding:		
Weighted average number of common shares outstanding for computing basic earnings per share	11,801,453	10,078,962
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	11,801,453	10,078,962
Net loss per share - basic and diluted	\$ (2.27)	\$ (0.36)

\* The following common stock equivalents are excluded from earnings per share calculation as their effect would have been antidilutive:

Year Ended December 31, -----	1998 -----	1997 -----
Warrants and stock options	7,102,242	4,073,309

F-11

#### SEGMENT REPORTING

As of January 1, 1998, the Company adopted Statement of Financial Accounting Standards No. 131 (SFAS 131), Disclosures about Segments of an Enterprise and Related Information Based upon definitions contained within SFAS 131, the Company has determined that it operates in one segment.

#### COMPREHENSIVE INCOME

The Statement of Financial Accounting Standards No. 130 (SFAS 130), "Reporting Comprehensive Income," establishes standards for reporting and display of comprehensive income. Comprehensive income includes charges or credits to equity that did not result from transactions with shareholders. SFAS No. 130 became effective during 1998. As net income and comprehensive income were identical in 1998 and 1997, SFAS No. 130 did not have an impact on the Company's financial statements.

#### RECENT PRONOUNCEMENTS

The Statement of Financial Accounting Standards No. 133 (SFAS 133), "Accounting for Derivative Instruments and Hedging Activities," becomes effective for the Company's year ending December 31, 2000. The Company does not believe that SFAS No. 133 will have a material impact on its financial statements.

#### 3. SHAREHOLDERS' EQUITY:

In March 1996, the Company commenced a private offering wherein 712,500 shares of common stock were sold for net proceeds of \$4,031,532, which included warrants to purchase 60,201 shares of common stock at \$9.00 per share. These warrants are exercisable through the earlier of five years from issuance or three years from the filing for an initial public offering.

In November 1996, the shareholders approved a reverse split of the Company's outstanding Common Stock on the basis of one share for each three shares of the then-outstanding common stock. The share information in the accompanying financial statements has been retroactively restated to reflect the reverse split. The Common Stock will continue to have \$.0001 par value. The shareholders approved the authorization of a new class of preferred stock which includes 2,000,000 shares at \$.0001 par value.

In May 1997, as a condition to its planned initial public offering, the Company offered to holders of 1,292,973 shares of its common stock, the right to rescind their purchase of shares of the Company's common stock. In July 1997, the Company completed its rescission offering to certain shareholders. In this offering, the Company repurchased 64,049 shares of its common stock for payments totaling \$408,419, which included interest expense of \$119,624.

In June 1997, in its initial public offering, the Company sold 2,000,000 units (the Units), each Unit consisting of one share of the Company's common stock, and one warrant to purchase one share of common stock for \$13.50. The Units separated immediately following issuance and now trade only as separate securities. Net proceeds of \$15,555,230 were received by the Company.



In July 1997, the Company's Underwriters exercised their over-allotment option and purchased 300,000 additional Units at \$9 per Unit, the initial public offering price. Proceeds of \$2,462,400 were received by the Company.

At December 31, 1998, the Company had two stock option plans, the 1992 Stock Incentive Plan and the 1997 Stock Option Plan (the Plans). The 1992 Plan provides for the issuance of incentive stock options to its employees and nonqualified stock options, stock appreciation rights and bonus rights to employees, directors of the Company and consultants. The 1997 Plan provides for the assumption of the ImmunoTherapy Options under the Merger Agreement. The Company has reserved 2,330,641 shares of common stock for issuance under the Plans. Options issued under the Plans generally vest ratably over four years and expire five to ten years from the date of grant.

The Financial Accounting Standards Board has issued SFAS 123, which defines a fair value based method of accounting for an employee stock option and similar equity instruments and encourages all entities to adopt that method of accounting for all of their employee stock compensation plans. However, it also allows an entity to continue to measure compensation cost for those plans using the method of accounting prescribed by Accounting Principles Board Opinion No. 25 (APB 25). Entities electing to remain with the accounting in APB 25 must make pro forma disclosures of net income (loss) and, if presented, earnings (loss) per share, as if the fair value based method of accounting defined in SFAS 123 had been adopted. The Company has elected to account for its stock-based compensation plans under APB 25; however, the Company has computed, for pro forma disclosure purposes, the value of all options granted during 1998 and 1997 using the Black-Scholes options pricing model as prescribed by SFAS 123 using the following weighted average assumptions for grants:

Year Ended December 31,	1998	1997
- - - - -	- - - - -	- - - - -
Risk-free interest rate	6.25%	6.25%
Expected dividend yield	0%	0%
Expected lives	6 Years	6 Years
Expected volatility	76%	56%

Using the Black-Scholes methodology, the total value of options granted during 1998 and 1997 was \$3,043,771 and \$1,984,033, respectively, which would be amortized on a pro forma basis over the vesting period of the options (typically four years). The weighted average fair value of options granted during 1998 and 1997 was \$4.08 and \$3.95, respectively. Included in options granted during 1998, are options assumed in connection with the ImmunoTherapy Corporation acquisition as discussed in Note 6. As the fair value of the assumed options was recorded as part of the purchase price allocation, these assumed options have not been included in the SFAS 123 fair value calculation.

If the Company had accounted for its stock-based compensation plans in accordance with SFAS 123, the Company's net income and net income per share would approximate the pro forma disclosures below:

For the Year Ended  
December 31,

	1998		1997	
	As Reported	Pro Forma	As Reported	Pro Forma
Net loss	\$ (26,733,963)	\$ (28,791,068)	\$ (3,615,990)	\$ (4,949,440)
Net loss per share - basic and diluted	\$ (2.27)	\$ (2.44)	\$ (0.36)	\$ (0.49)

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Additional awards are anticipated in future years.

A summary of the status of the Company's stock option plans and changes are presented in the following table:

For the Year Ended  
December 31,

	1998		1997	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	1,240,209	\$5.30	1,123,838	\$4.73
Granted	971,856	5.29	502,361	6.51
Exercised	(35,990)	4.64	(59,903)	4.70
Canceled	(39,181)	4.65	(326,087)	5.29
Options outstanding at end of year	2,136,894	5.32	1,240,209	5.30
Exercisable at end of year	1,428,798	\$5.05	980,206	\$5.01

At December 31, 1998, 193,747 shares were available for future grant.

F-14

The following table summarizes information about stock options outstanding at December 31, 1998:

Exercise Price	Outstanding Shares at December 31, 1998	Weighted Average Remaining Contractual Life (Years)	Exercisable Options
\$0.04	12,600	6.93	12,600
2.98	5,040	0.09	5,040
3.13	50,000	9.71	---
3.75	33,334	9.92	---
3.81	138,034	6.46	59,065
3.97	203,854	7.03	198,814
4.56	576,580	3.50	576,580
4.95	143,142	5.67	126,475

6.00	79,568	6.83	34,566
6.38	239,317	8.36	209,317
6.63	522,052	9.02	169,218
6.69	100,000	8.70	25,000
7.94	5,040	4.02	5,040
8.13	28,333	8.84	7,083

The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. The value of warrants granted in 1997 have not been considered in the fair value based method of accounting defined in SFAS 123 as such warrant grants related to the raising of additional equity. Of the 2,166,814 warrants granted during 1998, 2,116,814 were in connection with the ImmunoTherapy Corporation acquisition as discussed in Note 6. The fair value of such warrants was considered in the purchase price of ImmunoTherapy Corporation and therefore has not been considered in the fair value based method of accounting defined in SFAS 123. The remaining 50,000 warrants were granted to non-employees of the Company. A summary of the status of the Company's warrants and changes are presented in the following table:

For the Year Ended December 31,	1998		1997	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Warrants outstanding at beginning of year	2,833,101	\$12.88	427,434	\$4.42
Granted	2,166,814	13.36	2,700,000	13.30
Exercised	(34,567)	0.54	(50,000)	0.10
Canceled	---	---	(244,333)	5.39
Warrants outstanding at end of year	4,965,348	13.17	2,833,101	12.88
Exercisable at end of year	4,965,348	\$13.17	2,433,101	\$12.99

F-15

In connection with the initial public offering, the Company authorized the issuance of the Underwriters' Warrants (the Warrants) and reserved 400,000 shares of Common Stock for issuance upon exercise of such Warrants (including the warrants to purchase common stock issuable upon exercise of the Warrants). The Warrants entitle the holder to acquire up to an aggregate of 200,000 Units at an exercise price of \$10.80 per Unit and are exercisable one year from the date of the initial public offering. Each Unit consists of one share of Common Stock and one redeemable warrant. Each warrant initially entitles the holder thereof to purchase one share of Common Stock at a price of \$13.50 per share.

The following table summarizes information about warrants outstanding at December 31, 1998:

Exercise Price	Outstanding Warrants at December 31, 1998	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
\$ 0.0003	33,334	Varies	33,334

1.14	5,000	Varies	5,000
9.00	60,200	1.42	60,200
7.25	50,000	0.14	50,000
10.80	200,000	3.42	200,000
13.50	4,616,814	Varies	4,616,814

#### 4. INCOME TAXES:

At December 31, 1998 and 1997, the Company had federal and state tax net operating loss carryforwards of approximately \$23,900,000 and \$12,622,000, respectively. The difference between the operating loss carryforwards on a tax basis and a book basis is due principally to differences in depreciation, amortization, and treatment of research and development costs. The federal carryforwards began to expire in 1997 and the state carryforwards will begin to expire in 2008, if not otherwise used. Of this \$23,900,000, approximately \$4,150,000 relates to net operating losses assumed as part of the ImmunoTherapy Corporation acquisition. Utilization of such losses is limited to approximately \$1,200,000 per year. In addition, the Internal Revenue Code rules under Section 382 could limit the future use of the remaining \$19,750,000 in losses based on ownership changes and the value of the Company's stock.

The Company had a net deferred tax asset of \$10,566,000 and \$6,260,000 at December 31, 1998 and 1997, primarily from net operating loss carryforwards. A valuation allowance was recorded to reduce the net deferred tax asset to zero. The net change in the valuation allowance for deferred tax assets was an increase of approximately \$4,306,000 and \$1,600,000 for the years ended December 31, 1998 and 1997, respectively, mainly due to the increase in the net operating loss carryforwards.

F-16

An analysis of the deferred tax assets and liabilities as of December 31, 1998, is as follows:

	Deferred Tax Asset	Deferred Tax Liability	Total
Net operating loss carryforwards	\$ 9,569,000	\$ -	\$ 9,569,000
Depreciation	4,000	-	4,000
Research and development tax credits	1,285,000	-	1,285,000
Patent costs	-	(292,000)	(292,000)
	<u>\$ 10,858,000</u>	<u>\$ (292,000)</u>	<u>10,566,000</u>
Valuation allowance			(10,566,000)
			<u>\$ -</u>

An analysis of the deferred tax assets and liabilities as of December 31, 1997, is as follows:

	Deferred Tax Asset	Deferred Tax Liability	Total
Net operating loss carryforwards	\$ 5,049,000	\$ -	\$ 5,049,000
Accrued expenses	20,000	-	20,000
Depreciation	482,000	-	482,000
Research and development tax credits	930,000	-	930,000
Patent costs	-	(221,000)	(221,000)

	-----	-----	-----
	\$ 6,481,000	\$ (221,000)	6,260,000
	=====	=====	
Valuation allowance			(6,260,000)
			=====
			\$ -
			=====

#### 5. LEASE OBLIGATIONS:

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2004. Rent expense under these leases was \$293,000 and \$313,000 for the years ended December 31, 1998 and 1997, respectively, and \$1,440,000 for the period from July 22, 1980 through December 31, 1998.

At December 31, 1998, the aggregate noncancelable future minimum payments under these leases are as follows:

Year ending December 31,

1999	\$	325,000
2000		333,000
2001		341,000
2002		350,000
2003		335,000
Thereafter		298,000
		=====
Total minimum lease payments	\$	1,982,000
		=====

F-17

#### 6. ACQUISITION:

On September 15, 1998, the Company acquired all of the equity of ImmunoTherapy Corporation (ITC), a privately held biotechnology company based in Seattle, Washington. ITC was in the process of developing a therapeutic vaccine targeting cancer. The purchase consideration consisted of 2,132,592 shares of AVI BioPharma common stock and 2,116,814 warrants to purchase AVI BioPharma common stock. The transaction was accounted for as a purchase. In connection with the purchase price allocation, the Company estimated that substantially all of the intangible assets consist of research and development projects in process. At that time, the development of these projects had not reached technology feasibility and the technology was believed to have no alternative future use. In accordance with generally accepted accounting principles, a one-time charge for acquired in-process research and development of \$19,473,154, or \$1.65 per share, has been reflected in the accompanying financial statements.

The value assigned to purchased in-process technology was determined by estimating the costs to develop the purchased in-process technology into commercially viable products, estimating the resulting net cash flows from the expected product sales of such products, and discounting the net cash flows to their present value using a risk-adjusted discount rate.

Remaining development efforts for the acquired R&D projects include various stages of clinical testing and development work to manufacture the product in accordance with functional and commercial specifications. If none of these products is successfully developed, the sales and profitability of the combined company may be adversely affected in future periods.

Unaudited pro forma combined statements of operations assume the ITC acquisition occurred at beginning of each period and include acquired in-process research and development are as follows:

Year Ended December 31, -----	1998 -----	1997 -----
Revenues	\$120,351	\$ 14,345
Net loss	(27,684,092)	(4,940,483)
Net loss per share - basic and diluted	\$(2.08)	\$(0.40)

As part of the acquisition, the Company loaned \$440,000 in relocation related costs to a former ITC executive who joined the management of the Company. The resulting note receivable bears interest at 9 1/2 percent per year, is due March 31, 1999, and is included in Other current assets.

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As Independent public accountants, we hereby consent to the incorporation of our report dated January 27, 1999, included in this Form 10-KSB into the Company's previously filed registration Statement No. 333-34047 on Form S-8.

ARTHUR ANDERSEN LLP

Portland, Oregon,  
March 24, 1999

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