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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2000

/ / **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 incorporation or organization)	(I.R.S. Employer Identification No.)
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 with $.0001 par value
(Title of Class)

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Stock Market on February 28, 2001) was approximately $102,803,889. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on February 28, 2001 was 21,530,782.

Documents Incorporated by Reference

The issuer has incorporated into Part III of Form 10-K, by reference, portions of its Proxy Statement for its 2001 annual meeting.

AVI BIOPHARMA, INC.
FORM 10-K INDEX

PART I

Item 1. Description of Business

General Overview

Business

AVI BioPharma, Inc. (AVI) is a development-stage biopharmaceutical company focusing on developing therapeutic products using two distinct platform technologies: Cancer Immunotherapy and Gene-targeted drugs (NEU-GENES ®).

Our principal focus is developing treatments for life-threatening diseases, most notably cancer and heart disease. Currently approved drugs or other therapies often prove to be ineffective in treating advanced stages of these diseases or produce numerous unwanted side effects. Our two leading platforms, Cancer Immunotherapy and NEU-GENES, are specifically aimed at solving the challenges faced by today's pharmaceutical products. Each of these products represents large market opportunities.

Cancer Immunotherapy (Vaccines)

Avicine™, a therapeutic vaccine, represents our most advanced product opportunity, having completed a multi-center Phase II human clinical trial for colorectal cancer. Therapeutic cancer vaccines operate under the rationale that active immunization can stimulate an immune response that can be effective in fighting an existing cancer. The therapeutic benefit of the vaccine hinges on the existence of specific target sites, called tumor antigens, on cancer cells.

The target for Avicine is human chorionic gonadotropin (hCG). Not only is hCG responsible for stimulating fetal development during pregnancy, but it is also a tumor antigen on cancer cells of all major cancer types including cancers of the colon, pancreas, prostate, lung and breast. It is believed that the role of hCG in pregnancy and cancer is similar. In both cases, it (i) serves as a growth factor encouraging rapid cell division, (ii) fosters the formation of blood vessels, (iii) stimulates invasion of other tissues, and (iv) dampens the immune system to allow the fetus, or the tumor, to avoid rejection. Avicine is based on an anti-hCG approach to treating cancer.

Avicine has completed five clinical studies in cancer, in which a total of 172 patients received treatment. From these studies, we believe that the vaccine is a safe and essentially non-toxic therapy and capable of producing a specific immune response in most patients. Further, the patients who mounted an immune response to hCG lived longer than patients treated with other conventional therapies. We intend to investigate further the use of Avicine alone or in conjunction with other approved therapies in Phase II and Phase III trials.

Gene-Targeted Drugs (NEU-GENES)

We have developed third generation gene-inactivating compounds that we believe are more stable, specific, efficacious, and cost effective than other antisense or ribozyme agents. Our NEU-GENE compounds are distinguished by a novel backbone which replaces the natural or modified backbones of competing antisense or ribozyme technologies.

NEU-GENES use synthetic polymers to block the function of selected genetic sequences involved in disease processes. Targeting specific genetic sequences provides for greater selectivity than that available through conventional drugs. NEU-GENES have the potential to provide safe and effective treatment for a wide range of human diseases.

We have completed pre-clinical studies using our NEU-GENE compounds in the treatment of multiple types of cancer and in restenosis, the blockage of arteries following balloon angioplasty. We filed an Investigational New Drug application (IND) with the Federal Drug Administration (FDA) for Resten-NG™ for restenosis and began a Phase II clinical trial in late 2000.

Strategy

We have the experience and resources to initiate drug discovery and development, and move drug candidates through pre-clinical development and into early stage clinical trials (Phase I and Phase II). Our strategy for the near-term (2 to 5 years) is to license the marketing rights for our product candidates to pharmaceutical partners during or after Phase II clinical trials or co-develop product candidates with strategic partners. In this manner, expensive, late-stage clinical development and marketing will be the responsibility of the licensee. With adequate resources we may consider assuming greater responsibility for the late-stage clinical development and marketing opportunities of future product candidates.

This annual report includes our trademarks and registered trademarks, including Avicine and NEU-GENE. Each other trademark, trade name or service mark appearing in this annual report belongs to its holder.

Clinical Development Program

The following table summarizes our clinical development program.

Product Candidate	Pre-clinical	Phase I	Phase II	Phase III
Avicine™ (Colorectal Cancer Vaccine)	Completed	Completed	Completed	In progress
Avicine™ (Pancreatic Cancer Vaccine)	Completed	Completed	In progress	
Avicine™ (Prostate Cancer Vaccine)	Completed	Completed	Planned	
Resten-NG™ (NEU-GENE for Restenosis)	Completed	Completed	In progress	
Oncomyc-NG™ (NEU-GENE for Cancer)	Completed	Completed	Planned	
AVI-4126 (NEU-GENE for Polycystic Kidney Disease)	Completed	Planned	Planned	
AVI-4557 (NEU-GENE for P450)	Completed	Planned		
AVI-4014 (NEU-GENE for Inflammation)	In progress	Planned		
NeuBiotics™ (NEU-GENE Antibiotics)	In progress			

I. Cancer Immunotherapy

Avicine Therapeutic Cancer Vaccine

Technical Overview

The therapeutic vaccine approach is among the newer strategies being investigated for treating cancer. Historically, vaccines were developed and used to induce an immune response in order to prevent a disease. This is contrasted with a therapeutic vaccine approach where the disease entity is known or suspected to be present at the time of vaccination. The rationale employed with a therapeutic approach is that active immunization against a specific pathogenic agent can stimulate an immune response against the existing disease.

In order for a therapeutic vaccine to be effective in fighting a disease such as cancer, it is necessary to identify specific target sites on the tumor cells, called tumor-associated antigens. The more selective that the antigen is to the tumor, the greater likelihood of attacking only the cancer cells. The identification of an appropriate target has been one of the greatest challenges in the development of a useful cancer vaccine.

AVI BioPharma's therapeutic cancer vaccine, Avicine, which is currently in clinical trials, is designed to produce an immune response against a well-characterized target, human chorionic gonadotropin (hCG). hCG is a hormone produced during pregnancy that plays a variety of roles in fostering the development of a fetus. Through extensive research, scientists found that hCG is also present in most cancers. In fact, cancer is believed to be the only significant exception to the normal hCG function during pregnancy. Given the selective production of hCG, we believe it represents a highly specific target for a therapeutic cancer vaccine.

The use of hCG as a cancer vaccine target may offer advantages over other potential tumor associated antigens.

- It is not usually found on normal cells with the exception of those present during a pregnancy. This means that it is highly selective.
- It is widely expressed by and found on many types of cancer, including colon, pancreas, prostate, lung and breast.
- hCG expression has been correlated with tumor aggressiveness. In other words, the higher the level of hCG, the more aggressive the rate of growth or spread of the cancer.
- Antibodies to hCG are believed to block the same hormonal functions that hCG plays in pregnancy and cancer, including rapid cell division, the formation of blood vessels, invasion of other tissues, and dampening of the immune responses.

Since hCG is a natural human protein, people will not mount an immune response to it unless they are actively immunized. Once immunized, the mechanism of action of an anti-hCG vaccine can be viewed as a two-pronged attack. First, it directs an immune response against the tumor, and second, it neutralizes the hormonal benefits provided by hCG.

The hCG component in Avicine is a small peptide from this hormone. The peptide is joined to a carrier, diphtheria toxoid, to enhance the immune response. Diphtheria toxoid was selected since most of the world's population has been vaccinated against it and there is significant experience with it as a vaccine component in man. The combination provides for an existing immune response to the carrier which is believed to be important in stimulating an immune response to the hCG peptide.

AVICINE'S DISTINGUISHING CHARACTERISTICS

- Fully-characterized synthetic vaccine
- Capable of being produced inexpensively in large quantities
- Targets a widely-expressed tumor antigen (hCG)
- Ready for Phase III clinical testing in colorectal patients
- Applicable to most cancer types in multiple clinical settings
- Twenty years of research and development and safety data

Avicine Clinical Trials

We have completed three Phase I clinical trials using Avicine in 87 patients with cancer. Overall, these studies showed Avicine to be safe and essentially non-toxic. These early clinical trials showed the vaccine to be effective in stimulating an immune response to hCG in most patients. Moreover, apparent survival benefits and some tumor regressions were noted.

Pancreatic and Prostate Cancer Trials

We have completed a pilot Phase II study using Avicine in 10 patients with advanced pancreatic cancer. For the 10 patients treated, the median survival was approximately 33 weeks. Patients with advanced pancreatic cancer are currently treated with chemotherapy and have a median survival of approximately 18 to 25 weeks. Although we believe these results are encouraging, we hesitate to draw conclusions from such a small study other than to use these results to design additional trials.

Two additional Phase II trials were scheduled. The first Phase II study of 50 patients with pancreatic cancer completed enrollment in 2000. In addition, we plan to initiate a Phase II clinical trial in 100 patients with prostate cancer in 2001.

Colorectal Cancer Trials

A multicenter Phase II study of Avicine was conducted in 77 patients with advanced colorectal cancer. The objectives of this trial were to determine whether administration of Avicine would induce an immune response in patients with metastatic colorectal cancer, and to measure safety and efficacy in these patients. Overall, 51 of the 77 patients responded to our 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.

Further analysis of the multicenter Phase II data showed that patients who produced antibodies to two targets on the hCG peptide had a median survival of 66 weeks. Camptosar®, the current standard of care for treating advanced colorectal cancer patients, produces a median survival of 37-40 weeks. Through additional research efforts, we believe we have learned how to improve production of antibodies to the two hCG targets in most patients.

Overall, these clinical data suggest that the patients that received Avicine and responded by making hCG antibodies had improved median survival compared to patients treated with chemotherapeutic drugs. Avicine was found to be safe and did not exhibit the toxicity associated with cytotoxic drug treatment. Based on these data, we plan to initiate a Phase III pivotal trial in 800 patients with metastatic colorectal cancer in 2001. This trial randomizes patients receiving first-line therapy for metastatic colorectal cancer to one of two treatment arms: combination chemotherapy or combination chemotherapy plus Avicine. The end points in the trial are time to disease progression and median survival.

AVICINE CLINICAL TRIALS

Trial	Description & Type	Patients	Status
1	Phase I safety study	43 treated	Completed
2	Phase I metastatic cancer	21 treated	Completed
3	Phase Ib metastatic cancer	23 treated	Completed
4	Phase II pancreatic and extension	10 treated	Completed
5	Phase II colorectal	77 treated	Completed
6	Phase II pancreatic	50	In progress
7	Phase II prostate	100	2001
8	Phase III colorectal licensing trial	800	In progress

II. Gene-Targeted Drugs—NEU-GENE Technology

Technical Overview

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 codes. Using modern methods of chemical synthesis, compounds can be prepared that recognize target gene sequences in a pathogen or pathogenic process. When these compounds bind tightly to the disease-causing sequence, the genetic process is inhibited, and thus the pathogen or pathogenic process is disabled. This is called *antisense* technology since the *sense* of the genetic code is blocked.

Limitations of then-existing antisense technology in the late 1980s led us to pursue a different approach than many of our competitors. This effort culminated in our development of a class of third-generation agents, known as NEU-GENE compounds. In pre-clinical studies, our patented compounds display advantageous pharmaceutical properties over second-generation compounds now in clinical trials by others. Such improvements include stability, specificity, potency, low toxicity and effectiveness.

Near-term Product Development—Cancer and Restenosis

The first application of our antisense technology is designed to treat diseases involving abnormal cell division, such as cancer, certain cardiovascular and inflammatory diseases, psoriasis, polycystic kidney disease and chronic graft rejection. The NEU-GENE target for these diseases is the gene component named c-myc. We have finished the pre-clinical development of two NEU-GENE agents, Resten-NG and Oncomyc-NG, and have filed an IND and completed a Phase I clinical trial for restenosis and cancer.

The table below summarizes our broader development program for NEU-GENE:

NEUGENE ANTISENSE DEVELOPMENT PROGRAM

Antisense Target	Clinical Indication
C-myc	Cancer, restenosis, polycystic kidney disease
CYP 3A4	Metabolic redirection, cancer
NF kappa B	Arthritis, chronic inflammation
TNF alpha	Arthritis, septic shock, asthma
Bacterial ribosomes	Antibiotics for infectious diseases
Hepatitis C virus	Hepatitis

Collaborative Agreements

We believe that our vaccine and antisense technologies are broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To exploit our core technologies as fully as possible, our strategy is to enter into collaborative research agreements with major pharmaceutical companies for all cancer applications with our vaccine, and agreements directed at specific molecular targets for our NEU-GENE antisense technology. It is anticipated that NEU-GENE antisense collaborative research agreements may provide us with some funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional individual molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from their collaborative research programs. We intend to retain manufacturing rights to our antisense products. There can be no assurance, however, that we will be able to enter into collaborative research agreements with large pharmaceutical companies on terms and conditions satisfactory to us.

Manufacturing

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

We currently intend to retain manufacturing rights to all products incorporating our proprietary and patented antisense technology, whether such products are sold directly by us or through collaborative agreements with industry partners. Our current production capacity is insufficient for the requirements of human clinical studies. We have, however, commenced construction of a GMP facility which will have capacity to meet our Phase I and Phase II NEU-GENE clinical trial requirements for the foreseeable future. We have also contracted with a GMP facility to produce our near-term antisense therapeutic candidates for current pre-clinical and clinical trial studies. There is no assurance, however, that our plans will not change as a result of unforeseen events.

In March 1993, we moved to our present laboratory facility. This facility and the laboratory procedures followed by us 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. We 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

We plan to market the initial products when developed, and for which we obtain 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 we develop, and our financial resources. We do 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, we expect to enter into licensing, distribution, or partnering agreements with pharmaceutical companies that have large, established sales organizations. The timing of our 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 our 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 our marketing strategy therefore may not be implemented for several years. See "Drug Approval Process and Other Governmental Regulation."

Patents and Proprietary Rights

We have developed or acquired a comprehensive body of intellectual rights. The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. We plan to prosecute and aggressively defend our patents and proprietary technology. Our policy is to patent the technology, inventions, and improvements that are considered important to the development of our business. We also depend upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

We own forty-six patents covering various facets of our current technology platforms and future developmental technologies. We have additional pending applications in the areas of our Avicine, NEU-GENE, and other technologies. We intend to protect our proprietary technology with additional filings as appropriate.

We have acquired certain product/technology licenses from The Ohio State University and Dr. Vernon Stevens. These properties include exclusive world-wide licenses covering the composition, manufacturing and use of Avicine in all fields of use, with the exception of fertility regulation. Our proprietary rights also include the unrestricted use of vaccine technology for non-hormonal cancer applications. We enjoy the right to commercialize any new intellectual property relating to our licensed subject matter including access and use of all new experimental data resulting from Dr. Stevens' research. Our licenses have been granted for a period of thirty (30) years or ten (10) years from the expiration of the last issued patent, whatever comes later. Under these licensing agreements, we have the right to sublicense our products and technology throughout the world. For such rights, we are obligated to pay the licensors minimum annual royalties of $60,000 through the third quarter of 2001 and $55,000 thereafter. Subject to such minimums, the royalties are 5% of net sales of products from licensed technology in the United States and Canada; 2% of net sales in countries of the "European Economic Community"; and 25% of any royalties received by us for sublicenses in the United States, the "European Economic Community" or in Korea, subject to certain maximums.

There can be no assurance that any patents we apply for will be granted or that patents held by us will be valid or sufficiently broad to protect our technology or provide a significant competitive advantage. Additionally, we cannot provide assurance that practice of our patents or proprietary technology will not infringe third-party patents.

Although we believe that we have independently developed our technology and we attempt to ensure that our technology does not infringe the proprietary rights of others, if infringement were alleged and proven, there can be no assurance that we could obtain necessary licenses on terms and conditions that would not have an adverse effect on us. We are not aware of any asserted or unasserted claims that our technology violates the proprietary rights of any person.

Drug Approval Process and Other Government Regulation

The United States system of new drug approvals is the most rigorous in the world. It costs an average of $500 million and takes an average of almost 15 years from the discovery of a compound to bring a single new pharmaceutical to market. For every 5,000 to 10,000 chemically synthesized molecules screened, only 250 are ever issued an Investigational New Drug Application and tested in humans. Of those, the FDA will approve only one for commercialization according to the Pharmaceutical Research and Manufacturers of America. Yet, in recent years, societal and governmental pressures have created the expectation that biotech and pharmaceutical companies will reduce the costs for drug discovery and development 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, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a "screening lead", or starting point for drug development, isolation and structural determination may begin. The development process results in numerous chemical modifications to the screening lead in an attempt to improve the drug properties of the lead. After a compound emerges from the above process, the next steps are to conduct further preliminary studies on the mechanism of action, further IN VITRO (test tube) screening against particular disease targets and finally, some IN VIVO (animal) screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results are positive, the compound emerges from the basic research mode and moves into the preclinical phase.

Preclinical Testing

During the preclinical 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 typically take approximately three and one-half years to complete.

Investigational New Drug Application

During the preclinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective, if not rejected by the FDA, within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. In addition, an Institutional Review Board, comprised of physicians at the hospital or clinic where the proposed studies will be conducted, must review and approve the IND. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA.

Some limited human clinical testing may be done under a Physician's IND in support of an IND application and prior to receiving an IND. A Physician's IND is an IND application that allows a single individual to conduct a clinical trial under less rigorous standards with a shorter FDA review process. A Physician's IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Phase I Clinical Trials

After an IND becomes effective, Phase I human clinical trials can begin. These tests, involving usually between 20 and 80 healthy volunteers, typically take approximately one year to complete. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase I trials are normally not conducted for anticancer product candidates.

Phase II Clinical Trials

In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 volunteer patients with the targeted disease. The preliminary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately two years, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

Phase III Clinical Trials

This phase typically lasts about three years and usually involves 1,000 to 3,000 patients. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions that may result from long-term use of the drug.

New Drug Application

After the completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, a New Drug Application (NDA) is filed with the FDA. The NDA must contain all of the information on the drug gathered to that 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 1997 was 16.2 months, down from 23 months in 1996.

Marketing Approval

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

Phase IV Clinical Trials and Post Marketing Studies

In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

Competition

Companies in the cancer vaccine development area include Progenics, Corixa, Biomira, Bristol Meyers-Squibb, and E. Merck. Several companies are pursuing the development of antisense technology, including Glaxo, Boehringer Ingelheim, Genta, 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 our NEU-GENE compounds. While we believe 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 us and have more established collaborative relationships with industry partners than we do. We believe that the combination of pharmaceutical properties of our NEU-GENE compounds for cancer and restenosis afford us competitive advantages when compared with the antisense compounds of competitors.

We can also expect to compete with other companies exploiting alternative technologies that address the same therapeutic needs as do our technologies. 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 us.

Research and Development

The Company expensed $9,268,330, $6,672,027 and $6,306,860 on research and development activities during the years ended December 31, 2000, 1999 and 1998.

On September 15, 1998, we acquired all of the equity of ImmunoTherapy Corporation (ITC), a privately held biotechnology company based in Seattle, Washington. The purchase consideration consisted of 2,132,592 shares of our common stock and 2,116,814 warrants to purchase our common stock. The transaction was accounted for as a purchase. In connection with the purchase price allocation, we 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 our financial statements for the year ended December 31, 1998.

Employees

As of December 31, 2000, we had 71 employees, 24 of whom hold advanced degrees. Sixty-three employees are engaged directly in research and development activities, and eight are in administration. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Item 2. Description of Property

We occupy 30,900 square feet of leased laboratory and office space at 4575 S.W. Research Way, Suite 200, Corvallis, Oregon 97333. Our executive office is located in 2,400 square feet of leased space at One S.W. Columbia, Suite 1105, Portland, Oregon 97258. We believe that our facilities are suitable and adequate for our present operational requirements and that we are not dependent upon any individually leased premises.

Item 3. Legal Proceedings

As of February 28, 2001, there were no material, pending legal proceedings to which we are a party. From time to time, we become involved in ordinary, routine or regulatory legal proceedings incidental to our business.

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

No matters were submitted to a vote of our shareholders during the quarter ended December 31, 2000.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Our 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 for each quarterly period in the two most recent fiscal years and quarter-to-date for the next fiscal year:

1999		
Quarter 1	$ 4.09	$ 2.47
Quarter 2	5.00	2.94
Quarter 3	5.88	3.00
Quarter 4	7.94	2.88
2000		
Quarter 1	$ 26.19	$ 5.44
Quarter 2	14.50	8.06
Quarter 3	10.00	6.41
Quarter 4	7.31	4.06
2001		
Quarter 1 to February 28, 2001	$ 6.88	$ 4.31

The number of shareholders of record and approximate number of beneficial holders on February 28, 2001 was 641 and 9,600, respectively. There were no cash dividends declared or paid in fiscal years 2000 or 1999. We do not anticipate declaring such dividends in the foreseeable future.

In November 2000, we issued 7,769 shares of common stock to twenty-two employees at $5.45 per share for $42,372, under our Employee Stock Purchase Plan. The issuance of shares described above were in reliance on Section 4 (2) of the Securities Act of 1933, as amended. These shares have been registered with the Securities Exchange Commission using form S-8. We made no public solicitation in connection with the issuance of the above securities nor were there any other offerees. We relied on representations from the recipients of the securities that they purchased the securities for investment for their own account and not with a view to, or for resale in connection with, any distribution thereof and that they were aware of our business affairs and financial condition and had sufficient information to reach an informed and knowledgeable decision regarding their acquisition of the securities.

Item 6. Selected Financial Data

The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with the financial statements and notes thereto appearing in Item 14 of Part IV of this Report.

	Years Ended December 31,				
	2000	1999	1998	1997	1996
Operations data:					
Revenues	$ 1,297,338	$ 17,024	$ 120,351	$ 14,345	$ 27,227
Research and development	9,268,330	6,672,027	6,306,860	2,737,172	1,729,554
General and administrative	2,270,302	1,745,491	1,621,381	1,282,214	613,811
Acquired in-process research and development	—	71,874	19,473,154	—	—
Net loss	(9,239,956)	(8,278,441)	(26,733,963)	(3,615,990)	(2,087,362)
Net loss per share—					
Basic and diluted	(0.49)	(0.62)	(2.27)	(0.36)	(0.25)
Cash flow from operations	(9,128,745)	(7,561,388)	(6,736,462)	(3,005,882)	(1,608,088)
Balance sheet data:					
Cash and investments	$ 32,112,099	$ 11,620,505	$ 8,510,020	$ 17,638,936	$ 3,041,229
Working capital	31,408,473	10,611,593	7,833,049	17,193,526	2,738,677
Total assets	35,088,393	12,929,628	10,192,083	18,782,214	4,248,899
Shareholders' equity	33,365,601	11,889,474	9,005,684	18,317,762	796,127

Item 7. Management's Discussion and Analysis or Plan of Operations

Forward-Looking Information

This report contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from the results expressed in, or implied by these forward-looking statements, including the results for fiscal 2001. When used in this report, the words "anticipate," "believe," "estimate," "expect" and similar expressions are intended to identify such forward-looking statements. Important factors, that have caused, or in the future could cause the Company's actual results to differ materially from those expressed in any forward-looking statements, include, among others, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by the FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in Item 7 of this Form 10-K and the Company's Securities and Exchange Commission filings, from time to time.

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest and grant revenue, we have had no material revenues from the sale of products or from other sources, and we do not expect material revenues for at least the next 12 months. We expect to continue to incur losses for the foreseeable future as we expand our research and development efforts. As of December 31, 2000, our accumulated deficit was $60,293,833.

Results of Operations

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Year Ended December 31, 2000 Compared with Year Ended December 31, 1999. Revenues, from license fees, grants and research contracts, increased from $17,024 in 1999 to $1,297,338 in 2000 due primarily to the receipt of a $1,000,000 fee for expansion of an existing licensing arrangement. Operating expenses increased from $8,489,392 in 1999 to $11,538,632 in 2000 due to increases in research and development staffing and expenses associated with outside collaborations and pre-clinical and clinical testing of the Company's technologies. Additionally, increased general and administrative costs were incurred to support the research expansion, and to continue to broaden the Company's investor and public relations efforts. Net interest income increased from $193,927 in 1999 to $1,001,338 in 2000 due to earnings on increased cash balances.

Year Ended December 31, 1999 Compared with Year Ended December 31, 1998. Operating expenses decreased from $27,401,395 in 1998 to $8,489,392 in 1999 principally due to a one-time charge of $19,473,154 for acquired in-process research and development reflecting the acquisition of ImmunoTherapy Corporation (ITC) in September 1998 and, to a lesser extent, increases in research and development staffing and expenses associated with outside collaborations and pre-clinical testing of our technologies. Additionally, increased general and administrative costs were incurred to support the research expansion. Net interest income decreased from $547,081 in 1998 to $193,927 in 1999 due to smaller earnings on decreased cash balances.

Liquidity and Capital Resources

We have financed our operations since inception primarily through equity sales totaling $69,690,668 and grants and contract research funding of $2,138,555 from various sources. Our cash and cash equivalents were $25,898,513 at December 31, 2000, compared with $8,683,005 at December 31, 1999. The increase of $17,215,508 was primarily due to net proceeds of $19,861,571 from the Company's secondary offering completed August 1, 2000, net proceeds of $4,744,720 in a private equity placement from SuperGen, Inc. and $2,833,706 from the exercise of options and warrants, offset by $9,128,745 used in operations and $1,095,744 used for investing activities which consist primarily of purchases of property and equipment and patent related costs. In addition the Company's short-term securities increased $3,276,086 to $6,213,586 at December 31, 2000 due to receiving 347,826 registered shares of SuperGen, Inc. in a private equity placement, offset by unrealized losses in the value of these securities.

In July 2000, the Company completed a secondary offering for 3,000,000 shares of common stock at $7.25 per share. Net proceeds were $19,861,571. In addition, representatives' warrants to purchase 300,000 shares of AVI common stock were issued to the underwriters' of the secondary offering.

In April 2000, the Company entered into an alliance with SuperGen, Inc. for shared development and marketing rights for Avicine. Under the terms of the agreement, AVI and SuperGen will equally share in future clinical development and FDA registration costs as well as in profits from product sales in the United States. Additionally, AVI may receive up to $80 million from SuperGen from meeting commercialization benchmarks.

In addition, pursuant to a separate private placement, the Company received from SuperGen, Inc. $5,000,000 in cash and 347,826 registered shares of SuperGen, Inc. common stock in exchange for 1,684,211 shares of AVI common stock and a warrant to purchase 1,665,878 shares of AVI common stock, subject to anti-dilution provisions. Closing of the transaction occurred during the third quarter of 2000.

Our future expenditures and capital requirements will depend on numerous factors, including without limitation, the progress of our research and development programs, the progress of our 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, our ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of our products. Our cash requirements are expected to continue to increase each year as we expand our activities and operations. There can be no assurance, however, that we will ever be able to generate product revenues or achieve or sustain profitability.

We expect that our cash requirements over the next twenty-four months will be satisfied by existing cash resources. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility, nor do we intend to seek one.

Factors Affecting Future Operating Results

We do not provide forecasts of our future financial performance. While we are optimistic about our long-term prospects, the following factors should be considered in evaluating our outlook.

History of Operating Losses and Anticipated Future Losses

We incurred a net operating loss of $9.2 million in 2000. "Net operating loss" represents the amount by which our expenses (other than interest expense) exceed revenues. As of December 31, 2000, our accumulated deficit was $60.3 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from selling, general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

Early Stage of Product Development

Although we began operations in 1980, except for Avicine, we are only in the early stages of the development of our pharmaceutical products. We have devoted almost all of our time to research and development of our technology and products, protecting our proprietary rights and establishing strategic alliances. Our proposed products are in the pre-clinical or clinical stages of development and will require significant further research, development, clinical testing and regulatory clearances. We have no products available for sale and we do not expect to have any products available for sale for several years. Our proposed products are subject to development risks. These risks include the possibilities that any of the products could be found to be ineffective or toxic, or could fail to receive necessary regulatory clearances. Although we have obtained favorable results in Phase II using Avicine to treat colorectal cancer patients, we cannot assure that we will obtain similar results in the contemplated Phase III protocol. We have not received any significant revenues from the sale of products and we cannot assure investors that we will successfully develop marketable products, that our sales will increase or that we will become profitable. Third parties may develop superior or equivalent, but less expensive, products.

Lack of Operating Experience

We have engaged solely in the development of pharmaceutical technology. Although some of our management have experience in biotechnology company operations, we have limited experience in manufacturing or selling pharmaceutical products. We also have only limited experience in negotiating and maintaining strategic relationships, and in conducting clinical trials and other later-stage phases of the regulatory approval process. We cannot assure investors that we will successfully engage in any of these activities.

Need for Future Capital and Uncertainty of Additional Funding

Since we began operations, we have obtained operating funds primarily by selling shares of our company. Based on our current plans, we believe that current cash balances will be sufficient to meet our operating needs for approximately the next twenty-four months. Furthermore, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include the success of our research and development efforts, the status of our pre-clinical and clinical testing, costs relating to securing regulatory approvals and the costs and timing of obtaining new patent rights, regulatory changes, competition and technological developments in the market. We may need funds sooner than currently anticipated.

We anticipate that we will need to obtain additional funds during or at the end of this twenty-four month period. If necessary, potential sources of additional funding include strategic relationships, public or private sales of shares of our common stock or debt or other arrangements. We do not have any committed sources of additional financing at this time. It is uncertain whether we can obtain additional funding when we need it on terms that will be acceptable to us or at all. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing shareholders will be diluted. If we are unable to obtain financing when needed, our business and future prospects would be materially adversely affected.

Dependence on Others for Clinical Testing, Manufacturing and Marketing

We do not intend to conduct late-stage (Phase III) human clinical trials solely by ourselves. We anticipate entering into relationships with larger pharmaceutical companies to conduct later pharmaceutical trials and to market our products and we also plan to continue to use contract manufacturing for late stage clinical, and commercial quantities of our products. We may be unable to enter into corporate partnerships, which could impede our ability to bring our products to market. We cannot assure investors that any corporate partnerships, if entered, will be on favorable terms or will result in the successful development or marketing of our products. If we are unsuccessful in establishing advantageous clinical testing, manufacturing and marketing relationships, we are not likely to generate significant revenues and become profitable.

Limited Manufacturing Capability

While we believe that we can produce materials for Phase I and Phase II clinical trials at our existing facilities, we will need to expand our commercial manufacturing capabilities for products in the future if we elect not to or cannot contract with others to manufacture our products. This expansion may occur in stages, each of which would require regulatory approval, and product demand could at times exceed supply capacity. We have not selected a site for any expanded facilities and cannot predict the amount we will expend for construction of such facilities. We cannot assure if or when the FDA will determine that such facilities comply with Good Manufacturing Practices. The projected location and construction of any facilities will depend on regulatory approvals, product development, pharmaceutical partners and capital resources, among other factors. We have not obtained regulatory approvals for any productions facilities for our products, nor can we assure investors that we will be able to do so.

Governmental Regulation; Lack of Assurance of Regulatory Approvals

All of our products are subject to extensive regulation by the United States Food and Drug Administration and by comparable agencies in other countries. The FDA and comparable agencies require new pharmaceutical products to undergo lengthy and detailed clinical testing procedures and other costly and time-consuming compliance procedures. We cannot predict when we will initiate and complete our clinical trials or when we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in

obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies.

Dependence on Key Personnel

Our success will depend to a large extent on the abilities and continued service of several key employees, including Drs. Denis Burger, Patrick Iversen, David Mason, and Dwight Weller. The loss of any of these key employees could significantly delay the achievement of our goals. Competition for qualified personnel in our industry is intense, and our success will be dependent on our ability to attract and retain highly skilled personnel.

Competition

The biotechnology industry is highly competitive. We compete with companies in the United States and abroad that are engaged in the development of pharmaceutical technologies and products. They include:

- biotechnology, pharmaceutical, chemical and other companies;
- academic and scientific institutions;
- governmental agencies; and
- public and private research organizations.

Many of these companies and many of our other competitors have much greater financial and technical resources and production and marketing capabilities than we do. Our industry is characterized by extensive research and development and rapid technological progress. Competitors may successfully develop and market superior or less expensive products which render our products less valuable or unmarketable.

Patents and Proprietary Rights

Our success will depend on our existing patents and licenses, and our ability to obtain additional patents in the future. We have filed 64 patent applications in the United States, Canada, Europe, Australia and Japan and 46 patents have been issued. We license the composition, manufacturing and use of Avicine in all fields except fertility regulation from The Ohio State University, and we license other patents for certain complementary technologies from others.

We cannot assure investors that our pending patent applications will result in patents being issued in the United States or foreign countries. In addition, we cannot guarantee that patents which have been or will be issued will afford meaningful protection for our technology and products. Competitors may develop products similar to ours which do not conflict with our patents. Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of biotechnology firms generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the United States Patent and Trademark Office or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition, there is a substantial backlog of biotechnology patent applications at the USPTOs and the approval or rejection of patents may take several years.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others, as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action in order to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. We cannot be certain that any required license would be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected.

To help protect our proprietary rights in unpatented trade secrets, we require our employees, consultants and advisors to execute confidentiality agreements. However, we cannot guarantee that these agreements will provide us with adequate protection if confidential information is used or disclosed improperly. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets.

Potential Product Liability

The use of our products will expose us to the risk of product liability claims. Although we intend to obtain product liability insurance coverage, we cannot guaranty that product liability insurance will continue to be available to us on acceptable terms or that our coverage will

be sufficient to cover all claims against us. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses, lowering our earnings and, depending on revenues, potentially result in additional losses.

Uncertainty of Third-Party Reimbursement

In addition to obtaining regulatory approval, the successful commercialization of our products will depend on our ability to obtain reimbursement for the cost of the product and treatment. Government authorities, private health insurers and other organizations, such as health maintenance organizations are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the growth of healthcare organizations such as HMOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. The cost containment measures that healthcare providers are instituting and any healthcare reform could affect our ability to sell our products and may have a material adverse effect on our operations. We cannot assure investors that reimbursement in the United States or foreign countries will be available for any of our products, that any reimbursement granted will be maintained, or that limits on reimbursement available from third-party payors will not reduce the demand for, or the price of, our products. The lack or inadequacy of third-party reimbursements for our products would have a material adverse affect on our operations. We cannot forecast what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect the legislation or regulation would have on our business.

Risks Related to Share Ownership

Our Preferred Shares, Classified Board of Directors and Oregon Laws Could Prohibit Takeovers

Our authorized capital consists of 50,000,000 shares of common stock and 2,000,000 preferred shares. The Board of Directors, without any further vote by the shareholders, has the authority to issue preferred shares and to determine the price, preferences, rights and restrictions, including voting and dividend rights, of these shares. The rights of the holders of shares of common stock may be affected by the rights of holders of any preferred shares that the Board of Directors may issue in the future. For example, the Board of Directors may allow the issuance of preferred shares with more voting rights, higher dividend payments or more favorable rights upon dissolution, than the shares of common stock. If preferred shares are issued in the future, it may also be more difficult for others to acquire a majority of our outstanding voting shares.

In addition, we have a "classified" Board of Directors, which means that only one-half of our directors are eligible for election each year. Therefore, if shareholders wish to change the composition of the Board of Directors, it could take at least two years to remove a majority of the existing directors or to change all directors. Having a classified Board of Directors may, in some circumstances, deter or delay mergers, tender offers or other possible transactions which may be favored by some or a majority of our shareholders.

The Oregon Control Share Act and Business Combination Act limit parties who acquire a significant amount of voting shares from exercising control over us. The Act may lengthen the period for a proxy contest or for a person to vote their shares to elect the majority of our Board.

Volatility of Stock Price

Historically, the market price of our stock has been highly volatile. The following types of announcements could have a significant impact on the price of our common stock:

- positive or negative results of testing and clinical trials by ourselves or competitors
- delays in entering into corporate partnerships
- technological innovations or commercial product introductions by ourselves or competitors
- changes in government regulations
- developments concerning proprietary rights, including patents and litigation matters
- public concern relating to the commercial value or safety of any of our products
-

general stock market conditions

Further, the stock market has in recent months experienced and may continue to experience significant price and volume fluctuations. These fluctuations have particularly affected the market prices of equity securities of many biopharmaceutical companies that are not yet profitable. Often, the effect on the price of such securities is unrelated or disproportionate to the operating performance of such companies. These broad market fluctuations may adversely affect the ability of a shareholder to dispose of his shares at a price equal to or above the price at which the shares were purchased.

Future Sale of Eligible Shares May Lower the Price of our Common Stock

We have outstanding 21,508,148 shares of common stock and all are eligible for sale under Rule 144 or are otherwise freely tradeable. In addition:

- Our employees and others hold options to buy a total of 2,855,296 shares of common stock. The shares of common stock to be issued upon exercise of these options, have been registered, and therefore may be freely sold when issued;
- There are outstanding warrants to buy 7,394,861 shares of common stock. The shares issuable upon exercise of 4,416,814 warrants are registered. These shares may be freely sold when issued. The holders of warrants covering 400,000 shares have incidental registration rights to have the shares issuable upon the exercise of their warrants registered. Once registered, those shares may be freely sold when issued, for so long as the registration statement is effective and current. The remaining warrants have no registration rights.
- We may issue options to purchase up to an additional 82,281 shares of common stock under our stock option plans, which also will be fully saleable when issued.
- We are authorized to sell up to 242,231 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate.

Sales of substantial amounts of shares into the public market could lower the market price of our common stock.

Absence of Dividends

We have never paid dividends on our shares of common stock and do not intend to pay dividends in the foreseeable future.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Due to the short-term nature of our interest bearing assets we believe that our exposure to interest rate market risk is not significant.

Item 8. Financial Statements

All information required by this item begins on page F-1 in item 14 of Part IV of this Report and is incorporated into this item by reference.

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

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Information regarding our directors and executive officers required by this item is included in our definitive proxy statement for our 2001 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. Executive Compensation

The information required by this item is included in our definitive proxy statement for our 2001 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. Security Ownership of Certain Beneficial Owners and Management

The information required by this item is included in our definitive proxy statement for our 2001 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 13. Certain Relationships and Related Transactions

The information required by this item is included in our definitive proxy statement for our 2001 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 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a)

The following documents are filed as part of this Report:

Financial Statements

The following financial statements of the Company and the Report of Arthur Andersen LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

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 ImmunoTherapy Shareholders(3)
4.6	Form of Common Stock Purchase Warrant.(5)
10.1	1992 Stock Incentive Plan (as amended through May 11, 2000).(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)
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)

Exhibit No.	Description
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)
10.23	Purchase Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors(5)
10.24	Registration Rights Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors(5)
10.25	Purchase Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors(5)
10.26	Registration Rights Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors(5)
10.27	Subscription Agreement, dated December 1, 1999, by and between SuperGen, Inc. and AVI BioPharma, Inc.(5)
10.28	2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc.(6)
10.29	United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.
10.30	Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.(7)
10.31	Registration Rights Agreement, dated April 14, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.(7)
10.32	2000 Employee Share Purchase Plan(8)
23.0	Consent of Arthur Andersen LLP

(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).

(5) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-3, as amended, and filed with the Securities and Exchange Commission on December 21, 1999 (Commission Registration No. 333-93135).

(6) Incorporated by reference to exhibits to Registrant's Registration Statement on Form S-1 and filed with the Securities and Exchange Commission on June 16, 2000 (Commission Registration No. 333-39542).

(7) Incorporated by reference to exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on September 15, 2000 (Commission Registration No. 333-45888).

(8) Incorporated by reference to Appendix A to Registrant's Definitive Proxy Statement on Form 14-A, as amended, filed with the Securities and Exchange Commission on April 12, 2000.

(b) Reports on Form 8-K

The Company did not file any Reports on Form 8-K during the quarter ended December 31, 2000.

(c) Exhibits. See Item 14 (a) above.

(d) Financial Statement Schedules. See Item 14 (a) above.

SIGNATURES

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

Dated: February 28, 2001

AVI BIOPHARMA, INC.

By: /s/ DENIS R. BURGER, PH.D.

Denis R. Burger, Ph.D.
Chairman of the Board 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 February 28, 2001:

Signature	Title
/s/ DENIS R. BURGER, PH.D. Denis R. Burger, Ph.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
/s/ ALAN P. TIMMINS Alan P. Timmins	President, Chief Operating Officer, and Director
/s/ MARK M. WEBBER Mark M. Webber	Chief Financial Officer and Chief Information Officer (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/ NICK BUNICK Nick Bunick	Director
/s/ BRUCE L.A. CARTER, PH.D.	Director

Bruce L.A. Carter, Ph.D.	
/s/ JOHN W. FARA, PH.D.	Director
John W. Fara, Ph.D.	
/s/ JAMES B. HICKS, PH.D.	Director
James B. Hicks, Ph.D.	
/s/ JOSEPH RUBINFELD, PH.D.	Director
Joseph Rubinfeld, Ph.D.	

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, 2000 and 1999, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2000 and for the period from inception (July 22, 1980) to December 31, 2000. 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 auditing standards generally accepted in the United States. 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, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 and for the period from inception (July 22, 1980) to December 31, 2000, in conformity with accounting principles generally accepted in the United States.

Arthur Andersen, LLP

Portland, Oregon
February 7, 2001

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

	December 31, 2000	December 31, 1999
Assets		
Current Assets:		
Cash and cash equivalents	$ 25,898,513	$ 8,683,005
Short-term securities—available-for-sale	6,213,586	2,937,500
Other current assets	1,019,166	31,242
Total Current Assets	33,131,265	11,651,747
Property and Equipment, net of accumulated depreciation and amortization of $2,658,549 and $2,518,494	1,036,749	403,303
Patent Costs, net of accumulated amortization of $541,185 and $418,268	890,532	844,731
Other Assets	29,847	29,847

Total Assets	$ 35,088,393	$ 12,929,628
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,290,804	$ 727,673
Accrued employee compensation	431,988	312,481
Total Current Liabilities	1,722,792	1,040,154
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; 21,508,148 and 16,236,428 issued and outstanding	2,151	1,624
Additional paid-in capital	105,340,697	62,901,227
Accumulated other comprehensive income (loss)	(11,683,414)	40,500
Deficit accumulated during the development stage	(60,293,833)	(51,053,877)
Total Shareholders' Equity	33,365,601	11,889,474
Total Liabilities and Shareholders' Equity	$ 35,088,393	$ 12,929,628

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

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

	Year ended December 31,			July 22, 1980 (Inception) to December 31, 2000
	2000	1999	1998	
Revenues, from license fees, grants and research contracts	$ 1,297,338	$ 17,024	$ 120,351	$ 2,138,555
Operating expenses:				
Research and development	9,268,330	6,672,027	6,306,860	33,995,963
General and administrative	2,270,302	1,745,491	1,621,381	11,468,970
Acquired in-process research and development	—	71,874	19,473,154	19,545,028
	11,538,632	8,489,392	27,401,395	65,009,961
Other Income:				
Interest income, net	1,001,338	193,927	547,081	2,480,823
Realized gain on sale of short-term securities	—	—	—	96,750
	1,001,338	193,927	547,081	2,577,573
Net loss	$ (9,239,956)	$ (8,278,441)	$ (26,733,963)	$ (60,293,833)
Net loss per share—basic and diluted	$ (0.49)	$ (0.62)	(2.27)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	18,724,533	13,440,205	11,801,453	

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

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

	Partnership Units	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT JULY 22, 1980 (Inception)	—	—	$ —	$ —	$ —	$ —	$ —
Issuance of partnership units, warrants and common stock	3,615	8,272,916	828	33,732,654	—	—	33,733,482
Compensation expense related to issuance of warrants for common stock and partnership units	—	—	—	537,353	—	—	537,353
Exercise of warrants for partnership units and common stock	42	1,214,263	121	184,046	—	—	184,167
Exercise of options for common stock	—	59,903	6	281,804	—	—	281,810
Conversion of debt into common stock and partnership units	9	9,634	1	87,859	—	—	87,860
Issuance of common stock in exchange for partnership units	(1,810)	1,632,950	163	(163)	—	—	—
Withdrawal of partnership net assets upon conveyance of technology	(1,856)	—	—	(176,642)	—	—	(176,642)
Common stock subject to rescission, net	—	(64,049)	(6)	(288,789)	—	—	(288,795)
Net loss	—	—	—	—	—	(16,041,473)	(16,041,473)
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
Exercise of warrants for common stock	—	16,667	2	3	—	—	5
Exercise of options for common stock	—	16,448	1	66,722	—	—	66,723
Issuance of common stock and warrants for cash and securities, net of offering costs	—	2,857,147	286	11,054,717	—	—	11,055,003
Comprehensive income (loss):							
Unrealized gain on short-term securities—available-for-sale	—	—	—	—	40,500	—	40,500
Net loss	—	—	—	—	—	(8,278,441)	(8,278,441)
Comprehensive loss							(8,237,941)
BALANCE AT DECEMBER 31, 1999	—	16,236,428	1,624	62,901,227	40,500	(51,053,877)	11,889,474
Exercise of warrants for common stock	—	162,215	16	1,103,438	—	—	1,103,454
Exercise of options for common stock	—	376,616	38	1,687,842	—	—	1,687,880
Issuance of common stock for ESPP	—	7,769	1	42,371	—	—	42,372
Issuance of common stock and warrants for cash and securities, net of offering costs	—	4,725,120	472	39,605,819	—	—	39,606,291
Comprehensive loss:							
Unrealized loss on short-term securities—available-for-sale	—	—	—	—	(11,723,914)	—	(11,723,914)
Net loss	—	—	—	—	—	(9,239,956)	(9,239,956)
Comprehensive loss							(20,963,870)
BALANCE AT DECEMBER 31, 2000	—	21,508,148	$ 2,151	$ 105,340,697	$ (11,683,414)	$ (60,293,833)	$ 33,365,601

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

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

	Year ended December 31,			For the Period July 22, 1980 (Inception) to December 31, 2000
	2000	1999	1998	
Cash flows from operating activities:				
Net loss	$ (9,239,956)	$ (8,278,441)	$ (26,733,963)	$ (60,293,833)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	416,497	313,238	223,186	3,470,028
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	—	71,874	19,473,154	19,545,028
(Increase) decrease in:				
Other current assets	(987,924)	478,186	(490,386)	(1,019,166)
Other assets	—	—	—	(29,847)
Net increase (decrease) in accounts payable and accrued liabilities	682,638	(146,245)	721,947	1,722,792
Net cash used in operating activities	(9,128,745)	(7,561,388)	(6,736,462)	(35,879,543)
Cash flows from investing activities:				
Proceeds from sale or redemption of short-term investments	—	—	—	247,750
Purchase of property and equipment	(813,187)	(135,075)	(109,657)	(3,795,073)
Patent costs	(282,557)	(283,409)	(264,434)	(1,602,236)
Acquisition costs	—	(71,874)	(2,203,236)	(2,377,616)
Net cash used in investing activities	(1,095,744)	(490,358)	(2,577,327)	(7,527,175)
Cash flows from financing activities:				
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	27,439,997	8,224,731	184,873	69,690,668
Buyback of common stock pursuant to rescission offering	—	—	—	(288,795)
Withdrawal of partnership net assets	—	—	—	(176,642)
Issuance of convertible debt	—	—	—	80,000
Net cash provided by financing activities	27,439,997	8,224,731	184,873	69,305,231
Increase (decrease) in cash and cash equivalents	17,215,508	172,985	(9,128,916)	25,898,513
Cash and cash equivalents:				
Beginning of period	8,683,005	8,510,020	17,638,936	—
End of period	$ 25,898,513	$ 8,683,005	$ 8,510,020	$ 25,898,513
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:				
Short-term securities—available-for-sale received in connection with the private offering	$ 15,000,000	$ 2,897,000	$ —	$ 17,897,000
Unrealized gain (loss) on short-term securities —available-for-sale	$ (11,723,914)	$ 40,500	$ —	$ (11,683,414)

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

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND NATURE OF BUSINESS:

AVI BioPharma, Inc. (the Company or AVI) 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 cancer immunotherapy technology.

Through May 1993, the financial statements included 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 through that date 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 through that date 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. 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 then 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 4.05 percent of gross revenues in excess of $200 million, 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.

In March 2000, the Company and AGDG amended the Technology Transfer Agreement to give to AGDG and Gene Tools LLC, related organizations, exclusive, non royalty-bearing rights to in vitro diagnostic applications of the intellectual property. In consideration for this amendment, Gene Tools paid the Company $1 million and reduced the royalty that the Company would pay to AGDG under the Technology Transfer Agreement on future sales of therapeutic products from 4.05% to 3.00%.

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.

The Company is in the development stage. Since its inception in 1980 through December 31, 2000, the Company has incurred losses of approximately $60 million, substantially all of which resulted from expenditures related to research and development, general and administrative expenses and a one-time charge in 1998 of $19,473,154 for acquired in-process research and development reflecting the acquisition of ImmunoTherapy Corporation. 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 accounting principles generally accepted in the United States 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 from the date of purchase to be cash equivalents.

Short-Term Securities—Available-For-Sale

The Company accounts for its short-term securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). As such, the Company has classified its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value, which was below cost by $11,683,414 at December 31, 2000. The unrealized difference between the cost and the fair market value of these securities has been reflected as a separate component of shareholders' equity. These short-term securities represent common stock of SuperGen, Inc. with a fair value of $6,213,586 at December 31, 2000.

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.

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.

Year Ended December 31,	2000	1999	1998
Net loss	$ (9,239,956)	$ (8,278,441)	$ (26,733,963)
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	18,724,533	13,440,205	11,801,453
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	18,724,533	13,440,205	11,801,453
Net loss per share—basic and diluted	$ (0.49)	$ (0.62)	$ (2.27)

*

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

Year Ended December 31,	2000	1999	1998
Warrants and stock options	10,250,157	7,722,621	7,102,242

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. The Company's only component of "other comprehensive income (loss)" is unrealized gain (loss) on short-term securities available-for-sale.

Recent Pronouncements

In June 1999, Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 137, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 137). SFAS 137 is an amendment to Statement of Financial Accounting Standards No. 133, "Accounting for Derivative and Hedging Activities." SFAS 137 is effective for the Company beginning January 1, 2001. The Company currently does not have any derivative instruments and, accordingly, does not expect the adoption of SFAS 137 to have an impact on its results of operations or financial position.

3. SHAREHOLDERS' EQUITY:

In December 1999, the Company completed a private offering with institutional investors and an equity sale to SuperGen, Inc., as a prospective corporate partner. In the private offering, 1,857,147 shares of common stock and 628,573 warrants to purchase common stock at $4.025 per share were issued. All of the warrants issued in connection with the private placement are currently exercisable and expire in five years from closing. Net proceeds of $5,808,003 were received from the private placement. In the equity sale to SuperGen, Inc., 1,000,000 shares were issued in exchange for net proceeds of $5,247,000 in cash and securities including 100,000 shares of SuperGen Inc.'s common stock. Subsequent to December 31, 1999, the shares received from SuperGen, Inc. were registered and have no restrictions.

In April 2000, the Company entered into an alliance with SuperGen, Inc. for shared development and marketing rights for Avicine. Under the terms of the agreement, AVI and SuperGen Inc. will equally share in future clinical development and FDA registration costs as well as in profits from product sales in the United States. Additionally, AVI may receive up to $80 million from SuperGen from meeting commercialization benchmarks. In addition, pursuant to a separate private placement, the Company received from SuperGen, Inc. $5,000,000 in cash and 347,826 registered shares of SuperGen, Inc. common stock in exchange for 1,684,211 shares of AVI common stock and a warrant to purchase 1,665,878 shares of AVI common stock, subject to anti-dilution provisions. Closing of the transaction occurred during the third quarter of 2000.

In July 2000, the Company completed a secondary offering for 3,000,000 shares of common stock at $7.25 per share. Net proceeds were $19,861,571. In addition, representatives' warrants to purchase 300,000 shares of AVI common stock were issued to the underwriters' of the secondary offering.

In 2000, the Board of Directors and the Company's shareholders approved the Employee Stock Purchase Plan under which the Company is authorized to sell up to 250,000 shares of common stock to its full-time employees, nearly all of whom are eligible to participate. Under the terms of the Plan, employees may elect every six months to have up to 10% of their compensation withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the beginning-of-plan period or end-of-plan period market price of the Company's common stock. During 2000, twenty-two employees elected to purchase 7,769 shares of the Company's common stock at $5.45 per share on November 15, 2000.

At December 31, 2000, 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 2,937,577 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 2000 and 1999 using the Black-Scholes options pricing model as prescribed by SFAS 123 using the following weighted average assumptions for grants:

Year Ended December 31,	2000	1999	1998
Risk-free interest rate	5.74%	6.25%	6.25%
Expected dividend yield	0%	0%	0%
Expected lives	6 Years	6 Years	6 Years
Expected volatility	147%	91%	76%

Using the Black-Scholes methodology, the total value of options granted during 2000, 1999 and 1998 was $6,310,098, $366,767 and $3,043,771, 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 2000, 1999 and 1998 was $6.07, $2.70 and $4.08, respectively. Included in options granted during 1998, are options assumed in connection with the ImmunoTherapy Corporation acquisition as discussed in Note 7. 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 loss and net loss per share would approximate the pro forma disclosures below:

For the Year Ended December 31,	2000		1999		1998	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net loss	$ (9,239,956)	$ (10,126,948)	$ (8,278,441)	$ (9,867,318)	$ (26,733,963)	$ (28,791,068)
Net loss per share—basic and diluted	$ (0.49)	$ (0.54)	$ (0.62)	$ (0.73)	$ (2.27)	$ (2.44)

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,	2000		1999		1998	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	2,195,367	$ 5.27	2,136,894	$ 5.32	1,240,209	$ 5.30
Granted	1,039,446	6.25	135,631	3.47	971,856	5.29
Exercised	(376,616)	4.48	(16,448)	4.06	(35,990)	4.64
Canceled	(2,901)	5.89	(60,710)	3.43	(39,181)	4.65
Options outstanding at end of year	2,855,296	5.73	2,195,367	5.27	2,136,894	5.32
Exercisable at end of year	1,751,547	$ 5.50	1,752,226	$ 5.17	1,428,798	$ 5.05

At December 31, 2000, 82,281 shares were available for future grant.

The following table summarizes information about stock options outstanding at December 31, 2000:

Exercise Price	Outstanding Shares at December 31, 2000	Weighted Average Remaining Contractual Life (Years)	Exercisable Options
$0.04	12,600	4.93	12,600
3.31	79,536	5.34	62,786
3.69	31,000	7.57	10,000
3.75	33,334	7.91	16,667
3.81	116,446	4.58	91,446
3.97	159,368	5.38	159,368
4.56	301,672	1.48	301,672

4.75	57,112	4.99	30,533
4.95	119,158	3.95	119,158
5.00	5,000	3.95	1,250
5.75	503,000	9.01	—
6.00	73,335	5.24	65,001
6.38	236,599	6.41	224,099
6.63	518,429	7.05	509,679
6.69	100,000	6.69	75,000
6.88	436,000	8.80	49,999
7.19	33,334	9.59	—
7.94	1,040	2.02	1,040
8.13	28,333	6.84	21,249
10.00	10,000	4.41	—

The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. Of the 2,115,878 warrants granted during 2000, 1,965,878 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. The value of warrants granted in 1999 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 7. 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. A summary of the status of the Company's warrants and changes are presented in the following table:

For the Year Ended December 31,	2000		1999		1998	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Warrants outstanding at beginning of year	5,527,254	$ 12.22	4,965,348	$ 13.17	2,833,101	$ 12.88
Granted	2,115,878	29.99	628,573	4.025	2,166,814	13.36
Exercised	(162,215)	8.04	(16,667)	0.0003	(34,567)	0.54
Canceled	(86,056)	4.41	(50,000)	7.25	—	—
Warrants outstanding at end of year	7,394,861	17.49	5,527,254	12.22	4,965,348	13.17
Exercisable at end of year	5,278,983	$ 12.48	5,455,825	$ 12.33	4,965,348	$ 13.17

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 currently exercisable and expire June 2002. 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, 2000:

Exercise Price	Outstanding Warrants at December 31, 2000	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
$0.0003	16,667	No expiration date	16,667
1.14	3,000	No expiration date	3,000
4.03	500,002	3.97	500,002
8.70	300,000	4.59	—
10.00	150,000	4.42	—
10.80	142,500	1.42	142,500
13.50	4,616,814	1.86	4,616,814
35.63	1,665,878	9.26	—

4. INCOME TAXES:

As of December 31, 2000 and 1999 the Company has net operating loss carryforwards of approximately $41,190,000 and $30,700,000, respectively, available to reduce future taxable income, which expire 2001 through 2020. Of this $41,190,000, 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 $37,040,000 in losses based on ownership changes and the value of the Company's stock. Approximately $1,796,000 of the Company's carryforwards were generated as a result of deductions related to exercises of stock options. When utilized, this portion of the Company's carryforwards, as tax effected, will be accounted for as a direct increase to contributed capital rather than as a reduction of that year's provision for income taxes. The principal differences between net operating loss carryforwards for tax purposes and the accumulated deficit result from depreciation, amortization, and treatment of research and development costs and deductions related to the exercise of stock options for income tax purposes.

The Company had a net deferred tax asset of $17,347,000 and $13,203,000 at December 31, 2000 and 1999, 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 $4,144,000 and $2,637,000 for the years ended December 31, 2000 and 1999, respectively, mainly due to the increase in the net operating loss carryforwards.

An analysis of the deferred tax assets and liabilities as of December 31, 2000, is as follows:

	Deferred Tax Asset	Deferred Tax Liability	Total
Net operating loss carryforwards	$ 16,064,000	$ —	$ 16,064,000
Depreciation	1,000	—	1,000
Research and development tax credits	1,629,000	—	1,629,000
Patent costs	—	(347,000)	(347,000)
	$ 17,694,000	$ (347,000)	17,347,000
Valuation allowance			(17,347,000)
			$ —

An analysis of the deferred tax assets and liabilities as of December 31, 1999, is as follows:

	Deferred Tax Asset	Deferred Tax Liability	Total
Net operating loss carryforwards	$ 12,278,000	$ —	$ 12,278,000
Depreciation	2,000	—	2,000
Research and development tax credits	1,261,000	—	1,261,000
Patent costs	—	(338,000)	(338,000)
	$ 13,541,000	$ (338,000)	13,203,000
Valuation allowance			(13,203,000)
			$ —

5. RELATED PARTY TRANSACTIONS:

In December 1999, the Company entered into an agreement with SuperGen, Inc. The president and chief executive officer of SuperGen, Inc. is a member of our Board of Directors. The chief executive officer of the Company is a member of the Board of Directors of SuperGen, Inc. Under terms of the agreement, the Company acquired $2.5 million cash and 100,000 shares of SuperGen, Inc. common stock, for 1,000,000 shares of AVI common stock. SuperGen, Inc. also acquired exclusive negotiating rights for the United States market for Avicine, the Company's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors.

In April 2000, the Company entered into an alliance with SuperGen, Inc. for shared development and marketing rights for Avicine as discussed in Note 3.

Effective May 19, 1993, the Company and AGDG entered into a Technology Transfer Agreement as discussed in Note 1.

In March 2000, the Company and AGDG amended the Technology Transfer Agreement as discussed in Note 1.

In December 2000, the Company loaned the chief executive officer of AVI $500,000. The term of the loan is one year. The loan is secured by the chief executive officer's stock in AVI. Interest will accrue at the rate of 8.5%.

6. LEASE OBLIGATIONS:

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2007. Rent expense under these leases was $405,000, $322,000 and $293,000 for the years ended December 31, 2000, 1999 and 1998, respectively, and $2,167,000 for the period from July 22, 1980 through December 31, 2000.

At December 31, 2000, the aggregate noncancelable future minimum payments under these leases are as follows:

Year ending December 31,	
2001	$ 513,000
2002	492,000
2003	506,000
2004	522,000
2005	537,000
Thereafter	1,099,000
Total minimum lease payments	$ 3,669,000

7. 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. The purchase consideration consisted of 2,132,592 shares of AVI 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 the period and include acquired in-process research and development are as follows:

Year Ended December 31,	1998
Revenues	$ 120,351
Net loss	(27,684,092)
Net loss per share—basic and diluted	$ (2.80)

8. FINANCIAL INFORMATION BY QUARTER (UNAUDITED):

2000 for quarter ended	December 31	September 30	June 30	March 31
Revenues from license fees, grants and research contracts	$ 25,000	$ 122,215	$ 18,250	$ 1,131,873
Operating expenses:				
Research and development	2,692,377	2,155,538	2,483,942	1,936,473
General and administrative	786,143	557,911	490,185	436,063
Acquired in-process research and development	—	—	—	—
	3,478,520	2,713,449	2,974,127	2,372,536
Other income:				
Interest income, net	445,963	339,130	115,464	100,781
Net loss	$ (3,007,557)	$ (2,252,104)	$ (2,840,413)	$ (1,139,882)
Net loss per share, basic and diluted	$ (0.14)	$ (0.11)	$ (0.17)	$ (0.07)

Shares used in per share calculations	21,477,556	20,303,112	16,710,194	16,359,671

1999 for quarter ended	December 31	September 30	June 30	March 31
Revenues from license fees, grants and research contracts	$ 9,241	$ 3,558	$ 110	$ 4,115
Operating expenses:				
Research and development	1,962,171	1,739,728	1,627,478	1,342,650
General and administrative	404,392	504,607	418,868	417,624
Acquired in-process research and development	10,537	—	1,498	59,839
	2,377,100	2,244,335	2,047,844	1,820,113
Other income:				
Interest income, net	31,143	35,696	50,549	76,539
Net loss	$ (2,336,716)	$ (2,205,081)	$ (1,997,185)	$ (1,739,459)
Net loss per share, basic and diluted	$ (0.17)	$ (0.17)	$ (0.15)	$ (0.13)
Shares used in per share calculations	13,713,993	13,351,206	13,351,206	13,349,358

QuickLinks

EXHIBIT 10.29

UNITED STATES OF AMERICA SALES, DISTRIBUTION, AND DEVELOPMENT AGREEMENT

This Sales, Distribution, and Development Agreement (the "Agreement") is made as of April 4, 2000 (the "Effective Date") by and between AVI BioPharma, Inc., ("AVI"), an Oregon corporation with its principal offices One SW Columbia, Suite 1105 Portland, Oregon 97258, and SuperGen Inc., a Delaware corporation ("SuperGen"), with its principal offices at Two Annabel Lane, Suite 220, San Ramon, California 94583.

RECITALS:

WHEREAS, AVI is developing a pharmaceutical compound known as Avicine (as defined below) for the treatment of colorectal cancer and other indications;

WHEREAS, AVI desires to collaborate with SuperGen with respect to the clinical development, obtaining of regulatory approvals, distribution and marketing of Avicine product(s) in the United States;

WHEREAS, SuperGen desires to collaborate with AVI with respect to such product(s); and

WHEREAS, SuperGen and AVI shall enter into that other certain agreement in support of their collaboration, a Common Stock Purchase Agreement, pursuant to which SuperGen will acquire an interest in AVI's common stock (the "Common Stock and Warrant Purchase Agreement", which, along with this Agreement, are collectively referred to as the "AVI-SuperGen Agreements");

NOW, THEREFORE, in consideration of the foregoing and the mutual covenant undertakings contained herein, the parties hereto hereby agree as follows:

ARTICLE I: DEFINITIONS

In addition to the other terms defined elsewhere herein, the following terms shall have the following meanings when used in this Agreement (and any term defined in the singular shall have the same meaning when used in the plural, and vice versa, unless stated otherwise):

1.1 "SuperGen Net Sales" means the total gross sales of the Product (as set forth on the invoice for such Product) by SuperGen and permitted Sublicensees (as defined in Article 2.5(a) below), Third Parties in the given calendar quarter or year, plus, if applicable, the fair market value of all properties and services received in consideration of a sale of Product by SuperGen and permitted Sublicensees to Third Parties during such calendar quarter or year, less the following deductions directly paid or incurred by SuperGen or its permitted Sublicensees with respect to the sale of the Product in such calendar quarter or year:

(i) with respect to the U.S. Territory, standard, percentage-based discounts, credits, rebates, including SuperGen's standard cash terms and returned goods, as well as rejections, recalls, bad debt write-offs, returns and retroactive price reductions in lieu of returns, and other discounts, credits, rebates (including but not limited to Medicare/

Medicaid Rebates), adjustments, allowances and management fees to group purchasing organizations and wholesaler fees; and

(ii) (A) chargebacks granted to drug wholesalers and (B) to the extent imposed by government authorities, retroactive rebates or other rebates.

1.2 "Affiliate" means any corporation or non-corporate business entity which controls, is controlled by, or is under common control with a Party. A corporation or non-corporate business entity shall be regarded as in control of another corporation or non-corporate business entity if it owns, or directly or indirectly controls, in excess of fifty percent (50%) of the voting stock of the other corporation, or (a) in the absence of the ownership of in excess of fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate business entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate business entity, as applicable.

1.3 "Competing Product" means any pharmaceutical product which is based on a vaccine technology targeting human chorionic gonadotropin (hCG) or its peptides used in oncology.

1.4 "Compound" means Avicine, known as a vaccine consisting of the c-terminal peptide of hCG conjugated to diptheria toxoid and formulated with nor muralyl dipeptide in a squalene emulsion Reg. No. BB IND 5907.

1.5 "Current Good Clinical Practice" means clinical practice as set out in: (i) current Guidelines for Good Clinical Practice for Trials on Medicinal Products in the European Union; (ii) US Code of Federal Regulations Title 21, Chapter 50 (Protection of Human Subjects), Chapter 56 (Institutional Review Boards), and relevant final FDA Guidance and Points to Consider for drugs and/or biotechnology-derived products, as may be amended from time to time; or (iii) the equivalent current law or regulation in any market.

1.6 "Current Good Laboratory Practice" means laboratory practice as set out in: (i) Rules Governing Medicinal Products in the European Union Vol. III, ISBN 92.825 9619-2 (ex. OECD principles of GLP), as may be amended from time to time; (ii) US Code of Federal Regulations, Title 21, Chapter 58 (Good Laboratory Practice for Nonclinical Laboratory Studies), and relevant final FDA Guidance and Points to Consider for drugs and/or biotechnology-derived products, as may be amended from time to time; or (iii) the equivalent current law or regulation in any market.

1.7 "Current Good Manufacturing Practice" means manufacture in accordance with: (i) EC Directive 91/456/EEC, as may be amended from time to time; (ii)the current principles and guidelines of Good Manufacturing Practice for medicinal products for human use as required by, but not limited to, the applicable sections of the US Federal Food, Drug and Cosmetic Act, the US Public Health Service Act, the US Code of Federal Regulations, Title 21, Parts 210 (CURRENT GOOD MANUFACTURING PRACTICE IN

MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL) and 211 (CURRENT GOOD MANUFACTURING PRACTICES FOR FINISHED PHARMACEUTICALS), and relevant final FDA Guidance and Points to Consider for drugs and/or biotechnology-derived products, as amended from time to time; or (iii) the equivalent current law or regulation in any market.

1.8 "Detail" means a face-to-face sales presentation by a Sales Representative during which the Product is marketed and promoted to an appropriate health care professional. This shall include, but not be limited to, discussions with health care professionals, meetings with or presentations to managed care entities, purchasing decision-makers or formulary committees of health care providers, and participation in conventions and continuing education programs.

1.9 "Detailing" means the act of marketing and promoting the Product through Details.

1.10 "FDA" means the U.S. Food and Drug Administration or any successor entity thereto.

1.11 "Finished Product" means the Product packaged and labeled for sale in accordance with applicable laws and regulations in the United States.

1.12 "Know-How" means any proprietary technology (other than the Licensed Patents) owned by or licensed (with a right of sublicense) to AVI during the term of this Agreement relating to the Compound or the Product; including but not limited to, all pharmacological and toxicological data, including animal test results and human clinical data and evaluation reports, and all performance specifications.

1.13 "Launch" means the date upon which the first commercial sale of a Product by SuperGen or its Affiliates to Third Parties (as evidenced by the invoice date for such sale) occurs in the United States.

1.14 "Licensed Patents" means all patents and patent applications set forth in Exhibit 1 throughout the United States, including without limitation substitutions, extensions, additions, reissues, reexaminations, renewals, divisions, continuations, continuations-in-part or supplementary patent certificates thereof or therefor, owned by or licensed (with the right to sublicense) to AVI during the term of this Agreement relating to the Compound and/ or the Product.

1.15 "Losses" means any liabilities, costs, damages, judgments, settlements and other reasonable out-of-pocket expenses (including legal and other professional fees and expenses).

1.16 "Marketing Studies" means those clinical trials and studies (including, for the purposes of this Agreement, physician-held IND studies) which are performed essentially for marketing purposes and expressly excludes all clinical studies and trials which are required to pursue, obtain, and maintain Regulatory Approval in the U.S. Territory.

1.17 "NDA" means, with respect to each commercially launched Product, an approvable New Drug Application filed by the Parties with the FDA for the U.S. Territory, and all subsequent submissions to that NDA.

1.18 "Net Units of Product Sold" means the total number of units of Product which are sold by SuperGen or its Affiliates to Third Parties during the given calendar quarter or year less any returned, recalled, damaged or any other such units of Product for which the customer has been credited the original sales price. For any given period, the Net Units of Product Sold shall equal that number of units of Product included in the calculation of SuperGen Net Sales for the same period.

1.19 "Party" means SuperGen or AVI, and "Parties" means SuperGen and AVI.

1.20 "Patent Protected" means, with respect to the Product in a specific

country, that the manufacture, use or sale of such Product in such country infringes a Valid Claim in such country.

1.21 "Person" means a natural person, a corporation, a partnership, a trust venture, any governmental authority, and any other entity or organization.

1.22 "Product" means any pharmaceutical product containing the Compound or a derivative thereof as an active ingredient.

1.23 "Product Sales" means the total gross sales of the Product.

1.24 "Promote" or "Promotion" means the act of Detailing or otherwise advertising, marketing and promoting sales of the Product and conducting as necessary Marketing Studies.

1.25 "Regulatory Approval" means with respect to the U.S. Territory, approval from the FDA to market a Product in the United States.

1.26 "Sales Representative" means, with respect to SuperGen, an individual:

(i) who is regularly employed by such Party on a full-time or part-time basis as a member of one of its sales forces or as a field-based medical liaison representative or, with the written consent of the other Party, is retained on a contractual basis to act as a part of its sales force; and

(ii) who is appropriately qualified and experienced in pharmaceutical product promotion to make effective sales presentations for the Product.

1.27 "Sales Year" means, for the first Sales Year, a twelve (12) month period commencing on the date of SuperGen's Launch of the Product in the U.S. Territory, or any succeeding twelve (12) month period.

1.28 "Specifications" means written manufacturing release specifications, which shall be agreed between the Parties for, respectively, the Compound, the Product and the Finished Product.

1.29 "AVI Technology" means the Licensed Patents and the Know-How.

1.30 "AVI Third Party Royalties" means the royalty payments made, for a given period during the term of this Agreement, by AVI to Ohio State University.

1.31 "AVI Trademark" means the trademark to be selected by AVI.

1.32 "Territory or Territories" means the United States of America.

1.33 "Third Party" means any Person that is not a Party or an Affiliate of a Party.

1.34 "U.S. Promotional Materials" means all electronic and computer managed information (including the Internet), all written, printed or graphic materials, brochures, sales aids and other promotional items relating to a Product approved by the U.S. Marketing Board for use in the U.S. Territory, including but not limited to advertising, Continuing Medical Education programs, audio programs, seminar presentations, symposia and speaker programs.

1.35 "U.S. Territory" means the continental United States of America, Hawaii and Alaska.

1.36 "U.S. Transfer Price" means the price for the sale of the Product by AVI to SuperGen in the U.S. Territory. The per unit U.S. Transfer Price will be equal to fifty percent (50%) of the SuperGen Net Sales divided by the Net Units of Product Sold in the most recent quarter.

1.37 "Valid Claim" means (a) an issued claim of any unexpired patent included among the Licensed Patents, or (b) a pending claim of any pending patent application included among the Licensed Patents, which has not been held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, which has not been rendered unenforceable through disclaimer or otherwise or which has not been lost through an interference proceeding.

ARTICLE 2: DISTRIBUTION AND PROMOTION

2.1 EXCLUSIVE DISTRIBUTOR. AVI hereby appoints SuperGen, and SuperGen hereby accepts appointment, as the exclusive distributor of the Product in the U.S. Territory, with the sole and exclusive right, exclusive even as to AVI, to sell commercially and to distribute the Product to Third Parties in the Territory, with the right to appoint Affiliate sub-distributors without AVI's prior consent, and with the right to appoint Third Party sub-distributors with AVI's prior written consent, which consent shall not be unreasonably withheld or delayed.

2.2 RESERVATION OF RIGHTS. Except as expressly provided in this Article 2 and elsewhere in this Agreement, no right, title or interest is granted, whether express or implied, by AVI to SuperGen relating to other AVI products. Nothing in this Agreement shall be deemed to restrict AVI's right to exploit technology, know-how, patents or any other intellectual property rights relating to other AVI products.

2.3 PROMOTION. AVI hereby grants to SuperGen, and SuperGen hereby accepts, the exclusive right, exclusive even as to AVI, to Promote the Product in the U.S. Territory, with the right to appoint Third Parties, and/or Affiliates to Co-Promote the Product in the U.S. Territory.

2.4 NON-COMPETE. During the term of this Agreement, the Parties shall not market, offer for sale or sell a Competing Product within the Territory.

2.5 LICENSE.

(a) AVI hereby grants SuperGen an exclusive license under the AVI Technology to offer to sell and sell the Product in the U.S. Territory, with the right to sub-license to Affiliates without AVI's prior consent, and with the right to sub-license to Third Parties (collectively the "Sublicensees") with AVI's prior written consent, such consent not to be unreasonably withheld or delayed. Such license shall be exclusive even as to AVI, except to the extent necessary to enable AVI to perform any obligations or activities that AVI is required or permitted to perform under this Agreement.

(b) Solely for the purpose of enabling SuperGen to exercise its rights pursuant to Article 8.5(b), (c), or (d) of this Agreement, AVI hereby grants SuperGen a non-exclusive license to make and have made the Product.

(c) If at any time during the term of this Agreement, the financial resources of AVI are not reasonably sufficient to enable it to continue to meet its obligations hereunder for at least the next six months, AVI will so notify SuperGen and the parties will meet to review and consider steps

that might be taken to preserve SuperGen's rights to the AVI Technology under the terms of the Agreement, including, but not limited to, the grant of a non-exclusive, royalty bearing license to SuperGen to develop, make, have made, import, have imported, use, sell, offer for sale, and otherwise exploit the Products in the U.S. Territory.

2.6 RIGHTS TO ADDITIONAL PRODUCTS.

(a) AVI hereby grants to SuperGen, and SuperGen hereby accepts, a right of first discussion with respect to all oncology compounds (except those covered by the certain existing license agreement between AVI and Abgenix dated January 6, 1999 other than the Compound, which are licensed to, owned by and/ or developed by AVI (regardless of their stage of development) as provided herein. If AVI desires to sell, or grant any rights relating to, any such compound, AVI shall first notify SuperGen in writing, and shall provide to SuperGen a data package which shall consist of all material information relating to such compound in the possession or control of AVI at such time, and shall also provide any other information in its possession or control reasonably requested by SuperGen for the evaluation of the compound and the business opportunity. Within sixty (60) days after the receipt of the data package and such other information, SuperGen shall notify AVI whether it is interested in such compound.

(b) If SuperGen notifies AVI that it is not interested in a particular compound, AVI shall have the right to commercialize such compound, by itself or with a Third Party, without restriction.

(c) If SuperGen notifies AVI of SuperGen's interest, the Parties shall, in good faith, negotiate the terms of an agreement under which AVI shall grant such rights to SuperGen. If the Parties are unable to agree to the terms of such an agreement, after good faith negotiations, within sixty (60) days from AVI's receipt of such notice pursuant to this Article 2.6(c), then AVI shall be free to grant such rights to any Third Party, provided that AVI shall not enter into an agreement which grants any rights to such compound to any Third Party on terms which, taken as a whole, are more favorable to such Third Party than those offered to SuperGen, without first offering such terms to SuperGen. If AVI offers such terms to SuperGen, then SuperGen shall have thirty (30) days in which to notify AVI as to whether SuperGen accepts such terms. If SuperGen accepts such terms, then the Parties shall promptly enter into such agreement, granting such rights to SuperGen.

(d) In licensing any compounds from Third Parties, AVI shall use its reasonable efforts to ensure that such compound can be offered to SuperGen in accordance with the provisions of this Article 2.6.

(e) The Right to Additional Products (Article 2.6) can not be transferred or assigned to another Party without the written consent of AVI; provided, SuperGen may assign or transfer such rights without AVI's consent (a) to its Affiliates, and (b) to an entity that acquires all or substantially all of the business or assets of SuperGen to which this Agreement pertains, whether by merger, reorganization, acquisition, sale or otherwise.

ARTICLE 3: CLINICAL DEVELOPMENT, PRODUCT APPROVAL AND LAUNCH

3.1 CLINICAL DEVELOPMENT COMMITTEE.

(a) CLINICAL DEVELOPMENT COMMITTEE. The Parties shall form a Clinical Development Committee which shall

(i) oversee, review and coordinate the implementation of (1) the clinical studies, and (2) the pursuit of Regulatory Approval in the U.S. Territory, including, but not limited to, the preparation and filing of the U.S. NDA;

(ii) be responsible for developing further clinical strategies for the Product in the U.S. Territory.

(iii) determine the Party responsible for managing the Clinical Development and Regulatory Approval activities.

(b) MEMBERSHIP. The Clinical Development Committee shall consist of no more than four (4) total members, with two representative from each Party. Each Party may replace its committee members at any time, with prior written notice to the other Party.

(c) MEETINGS. During the performance of the Clinical Development (as defined in Article 3.2), the Clinical Development Committee shall meet at least quarterly, or as otherwise agreed by the committee members. At its meetings, the Clinical Development Committee will: (i) formulate and review the Clinical Development and Regulatory Approval objectives, including, without limitation, formulating indications to be pursued, clinical studies to be conducted, and develop protocols for the clinical studies to be conducted; (ii) monitor the progress of the Clinical Development and Regulatory Approval toward their respective objectives; and (iii) review and approve a plan and budget for the Clinical Development and Regulatory Approval of the Product. With the consent of the committee members, other representatives of AVI and SuperGen may attend the Clinical Development Committee or subcommittee meetings as non-voting observers. Each party shall bear its own personal and travel costs and expenses relating to the Clinical Development Committee.

(d) DECISION MAKING. Except as set forth in this Article 3.1 (d), decisions of the Clinical Development Committee shall be made by unanimous approval of all members present; provided that at least one representative of each Party is present and so approves. In the event the required approval for a decision cannot be reached within thirty (30) days and all the members of each Party take the same opposing positions in a matter of importance, the matter shall be submitted to a senior executive from each of AVI and SuperGen, who shall meet and discuss in good faith to resolve such matter.

3.2 CLINICAL DEVELOPMENT.

SuperGen and AVI shall exercise their reasonable efforts to pursue, and each shall bear one half of the cost and expense of the Clinical Development of the Product to support Regulatory Approval for the treatment of colorectal and pancreatic cancer, or other indications as determined by the Clinical Development Committee, for the U.S. Territory incurred after the date of this Agreement. Each Party's share of the cost and expense of the Clinical Development of the Product will be paid to the Party managing the Clinical Development in cash. For purposes of this Agreement, "Clinical Development" includes but is not limited to all clinical studies and trials, and all safety, toxicology, efficacy, and other data required to pursue, obtain and maintain Regulatory Approval in the U.S. Territory, as well as the clinical studies established by the Clinical Development Comittee pursuant to Article 3.1. In performing its obligations under this Article 3.2, the Party managing the Clinical Development shall act in accordance with Article 3.4 below, and in so doing shall keep the other Party fully apprised with respect to its clinical development activities and shall provide the other Party with reasonable advance opportunity for input regarding these activities,

including the right to review and approve the protocols and audit reports relating to all clinical studies.

3.3 U.S. REGULATORY APPROVAL.

SuperGen and AVI shall exercise reasonable efforts to file, obtain and maintain Regulatory Approval for the Product in the United States, and to obtain reimbursement approval for the Product in the United States (including but not limited to any and all applicable programs administered by government and private third-Party payors), and shall each bear one half of the cost and expense thereof.

3.4 REASONABLE COOPERATION.

Each Party shall provide the other Party with all reasonable assistance requested by the other Party with respect to the foregoing U.S. clinical development and U.S. regulatory activities, including, but not limited to, promptly providing the other Party with any and all authorizations, approvals, certificates of free sale, and other information, documents, materials and assistance reasonably required by the other Party to file, obtain, and maintain U.S. Regulatory Approval for the Product. Out-of-pocket costs and expenses associated with these activities will be shared equally by the parties.

3.5 EXCUSED PERFORMANCE.

The Parties acknowledge and understand that the development, obtaining of Regulatory Approval, and marketing of the Product, as with any pharmaceutical product, is subject to certain inherent risks including that (a) the Product will be ineffective, toxic, or will not receive Regulatory Approval, or will receive Regulatory Approval but with labeling which the Parties agree is insufficient to render the Product commercially viable; (b) the Product will be too expensive to manufacture or market or will not achieve broad market acceptance; (c) Third Parties will hold proprietary rights that will preclude the marketing and sale of the Product; or (d) Third Parties will market equivalent or superior products. Neither Party makes any representation or warranty that the Product (i) will be successfully developed; (ii) will receive all necessary and/ or commercially viable Regulatory Approvals, (iii) will be Launched; or (iv) will be commercially successful. The respective obligations of the Parties under this Article 3, and Articles 4 and 5 below, are expressly conditioned upon the safety, efficacy and commercial feasibility of the Product, and, except as expressly provided herein, a Party's obligation hereunder shall be delayed or suspended for so long as any condition or event exists which reasonably causes a Party to question the safety, efficacy or commercial feasibility of the Product. Furthermore, SuperGen's obligation to market and Promote the Product in the Territory shall not apply if SuperGen has not commenced or has ceased marketing the Product in the U.S. substantially due to adverse business or financial conditions, including those caused by the regulatory authorities or other governmental authorities of the U.S., which would cause the marketing of such Product in such country to be contrary to the financial best interest of the Parties. Each Party shall promptly notify the other Party in the event any material issue arises as to the safety, efficacy, commercial feasibility, or adverse business or financial conditions with respect to any Product.

3.6 DEVELOPMENT EFFORTS. Both Parties shall ensure that the development activities undertaken pursuant to Article 3 and Article 4 hereof shall be carried out in accordance with Current Good Clinical Practice, Current Good Laboratory Practice and Current Good Manufacturing Practice.

3.7 GOOD CLINICAL PRACTICE AUDITS.

The parties shall appoint a mutually acceptable third party independent clinical research organization to conduct a Current Good Clinical Practice audit of the clinical development activities (a "GCP Audit"). The costs of both GCP Audits shall be borne by AVI and SuperGen. If SuperGen is the Party responsible for the clinical development and regulatory approval of the Product and if a GCP Audit reveals a material deficiency which AVI concludes, in its sole discretion, may jeopardize the success of the U.S. NDA filing for the Product, and if SuperGen does not rectify such deficiency to AVI's reasonable satisfaction within sixty (60) days of SuperGen's notice of such deficiency, then AVI shall thereafter have the right, but not the obligation, to assume responsibility for the Clinical Development and Regulatory Approval of the Product.

If AVI is the Party responsible for the clinical development and regulatory approval of the Product and if a GCP Audit reveals a material deficiency which SuperGen concludes, in its sole discretion, may jeopardize the success of the U.S. NDA filing for the Product, and if AVI does not rectify such deficiency to SuperGen's reasonable satisfaction within sixty (60) days of AVI's notice of such deficiency, then SuperGen shall thereafter have the right, but not the obligation, to assume responsibility for the Clinical Development and Regulatory Approval of the Product.

3.8 ACCESS TO DATA.

Promptly after the Effective Date and throughout the term of this Agreement, SuperGen and AVI shall each provide to the other, within a reasonable time, a shared database so that either party shall have ready access to all preclinical and clinical and manufacturing documentation, information and data resulting from Product research and development activities in the U.S. Territory, including, but not limited, case report forms, monitoring documents, patient informed consents, institutional review board approvals, medical and statistical programming and study reports for individual studies, clinical data summaries, and expert reports. Both Parties shall provide copies of such documentation and data upon request. Such information shall be considered to be Confidential Information (as defined in Article 13.1) of the disclosing Party, and shall only be used by the receiving Party for the purpose of obtaining U.S. regulatory approval of the Product.

3.9 IMPROVEMENTS.

At any time during the term of this Agreement, whether through the Clinical Development Committee or otherwise, if SuperGen or AVI severally or jointly develop any improvements, modifications, enhancements, additions to or extensions of the

Product (an "Improvement"), such Improvement shall be deemed to be a Product under this Agreement.

ARTICLE 4: PROMOTION

SuperGen shall use its reasonable efforts to Promote the Product in the

U.S. Territory. Final decisions with respect to Marketing Studies intended for use solely within the U.S. Territory shall be made by SuperGen.

ARTICLE 5: MILESTONE PAYMENTS

5.1 R & D PAYMENTS.

In consideration of past research and development performed by AVI, SuperGen shall make the following milestone payments to AVI, which payments shall be due and payable as set forth below and within thirty (30) days after the date or event specified. For the purposes of clarification, the Parties agree that the "first occasion" on which total Product Sales by SuperGen in the Territory reaches a specified amount, as referred to in Articles 5.1 below, shall be deemed to occur on the last date of the calendar month in which each such amount is reached.

(a) SuperGen will purchase Twenty Million Dollars ($20,000,000) in AVI common stock at the price, as determined by the Parties on the Effective Date (the "Initial Equity Investment"). The purchase price will be paid in a combination of Five Million ($5,000,000) in cash and Fifteen Million ($15,000,000) in SuperGen common stock. In addition, SuperGen will receive a warrant (the "Warrant") to purchase up to ten percent (10%) of the outstanding common stock of AVI at an exercise price equal to three hundred percent (300%) of the price of the Initial Equity Investment. The Warrant will be exercisable at any time, or from time to time, in whole or in part, for a three year period commencing on the earlier of the date the FDA accepts the NDA submitted for the Product or the date on which the Closing Price of AVI Common Stock exceeds the Warrant exercise price. The purchase of the AVI Common Stock and the terms of the Warrant are subject of a separate Common Stock and Warrant Purchase Agreement of even date.

(b) Two and One-Half Million Dollars ($2,500,000) SuperGen stock or cash, upon completion of accrual into the Phase III trial for the Product;

(c) Two and One-Half Million Dollars ($2,500,000) SuperGen stock or cash, upon acceptance by the FDA of the NDA submitted for the Product;

(d) Five Million Dollars ($5,000,000) SuperGen stock or cash, upon Launch of the Product in the U.S. Territory,

(e) Ten Million Dollars ($10,000,000) in cash, upon the occasion on which annual Product Sales by SuperGen in the Territory reach $100,000,000;

(f) Fifteen Million Dollars ($15,000,000) in cash, upon the occasion on which annual Product Sales by SuperGen in the Territory reach $250,000,000;

(g) Twenty Million Dollars ($20,000,000) in cash, upon the occasion on which annual Product Sales by SuperGen in the Territory reach $500,000,000; and

(h) Twenty-Five Million Dollars ($25,000,000) in cash, upon the first occasion on which annual Product Sales by SuperGen in the Territory reach $1,000,000,000.

5.2 EQUITY PAYMENTS LIMITATION.

The Parties acknowledge and agree that any and all milestone payments to be made by SuperGen pursuant to this Agreement as equity investments in AVI shall be subject to the terms and conditions of the Stock Purchase Agreement, which terms and conditions shall govern in the event of any inconsistency or conflict between this Agreement and the Stock Purchase

Agreement with respect to any equity investment in AVI by SuperGen. In particular, the Parties acknowledge and agree that in no event shall SuperGen be required to make any equity investment in AVI, through the payment of the equity milestones as set forth above or in any other manner, which would cause SuperGen to own in excess of nineteen point nine percent (19.9%) of the voting securities of AVI at any time; provided, however, that in the event that any equity investment to be made by SuperGen under this Agreement would cause SuperGen to own in excess of nineteen point nine percent (19.9%) of the voting securities of AVI, then SuperGen's obligation to make such equity investment shall be tolled for a period of two years. If AVI increases its share capital (other than by purchase of any equity in AVI by SuperGen) during such two year period, such that SuperGen would then be able to make such equity investment and would not thereby own in excess of nineteen point nine percent (19.9%) of the voting securities of AVI, AVI shall so notify SuperGen and SuperGen shall make such equity investment; provided that AVI may make only one such notification, with respect to the entire amount of such equity investment, during such two-year period. If by the end of such two year period AVI has not increased its share capital (other than by purchase of any equity in AVI by SuperGen) during such two year period, such that SuperGen would then be able to make such equity investment and would not thereby own in excess of nineteen point nine percent (19.9%) of the voting securities of AVI, then SuperGen shall have no further obligation to make such equity investment.

5.3 SINGLE PAYMENT OBLIGATION.

Each of the foregoing milestones set forth in Article 5.1 shall only be paid once regardless of the number of acceptances or Launches with respect to such Product, including multiple product forms of the same Compound, additional active or inactive ingredients, indications, modalities and/or dosage strengths.

With respect to the foregoing milestones set forth in Article 5.1 (e) through (h), in the event that SuperGen achieves more than any of one such milestones within the same calendar year, SuperGen shall not be obligated to pay more than the first of such milestones in such calendar year. Subject to the foregoing, SuperGen shall pay subsequent milestones upon their achievement in subsequent years.

5.4 METHOD OF PAYMENT.

All cash payments due under this Article 5 shall be paid by wire transfer or by such other means agreed upon by the Parties, in each case at the expense of SuperGen, with twenty-four (24) hours advance notice of each wire transfer, to the bank account(s) as AVI shall designate in writing following the occurrence of each cash milestone event.

ARTICLE 6: U.S. PROFIT SHARING

6.1 REPORTS BY SUPERGEN.

Within thirty (30) days from the end of each calendar quarter, SuperGen shall deliver to AVI a true and accurate written report showing the SuperGen Product Sales in the U.S. Territory for such calendar quarter. SuperGen shall calculate in this report the "U.S. Net Product Revenue" by subtracting from the U.S. Product Sales: (i) any discounts, returns, normal and customary rebates and cash and trade discounts actually taken, (ii) sales, use and/or other excise taxes and governmental charges actually paid in connection with the sales of Products, (iii) the cost of any bulk packages and packing, prepaid freight charges and insurance, (iv) amounts actually allowed or credited due to returns paid, and (v)

amounts written off to bad debt. It is understood and agreed that SuperGen shall not deduct from the U.S. Product Sales, costs and expenses associated with the marketing, promotion, detailing, and sales expenses, as detailed in Article 6.3.

6.2 U.S. PROFIT SPLIT.

Commencing on the date of acceptance by the FDA of the U.S. NDA for the Product, the U.S. Net Product Profits for each calendar year (or portion thereof less than a full calendar year) shall be shared equally between the Parties, fifty percent (50%) for AVI and fifty percent (50%) for SuperGen. The allocation of U.S. Net Product Profits between SuperGen and AVI as of the end of the applicable calendar quarter or year shall be called the "SuperGen U.S. Product Profit" and the "AVI U.S. Product Profit," respectively, which together shall equal the U.S. Net Product Profits as of the end of such period.

6.3 EXPENSES PAID BY SUPERGEN AND AVI.

All expenses related solely to the manufacturing and sale of the Product for the U.S. market, including the costs of marketing, promotion, detailing, sales, manufacturing, distribution, patent maintenance and license fees to Ohio State University based on U.S. sales shall be shared equally between SuperGen and AVI (the "Overhead Cost"). Within thirty (30) days from the end of each calendar quarter, each Party shall deliver to the other

Party a true and accurate written report showing its Overhead Cost incurred in manufacturing and selling the Product in the U.S. market for such calendar quarter.

6.4 FINAL PAYMENT.

After each calendar quarter, any amount payable by one Party to the other Party pursuant to this Article 6 ("Final Payment") shall be paid by the owing Party within ten (10) business days of AVI's receipt of SuperGen's report under Article 6.1. After each calendar quarter, any amount payable by one Party to the other Party pursuant to Article 6.3 above ("Overhead Payment") shall be paid by the owing Party within ten (10) business days of such Party's receipt of the other Party's report under Article 6.3.

6.5 YEAR-END RECONCILIATION.

Within forty-five (45) days after the end of each calendar year starting with the first calendar year for which the Parties have budgeted expenditures under Article 4, the U.S. Product Profit split between the Parties pursuant to Article 6.2 above and the Overhead Cost split between the Parties pursuant to Article 6.3 above for such calendar year shall be recalculated (the "Reconciliation Amount") to reflect any amended information (including, but not limited to, amended sales data, product returns, chargebacks, costs of marketing, promotion, detailing, sales and distribution) relevant to the calculation of the Reconciliation Amount for such calendar year. Within ten (10) business days after any such recalculation, the owing Party shall pay any amount due.

6.6 PAYMENT PROCEDURE.

All payments due under this Article 6 shall be paid in United States Dollars by wire transfer or by such other means agreed upon by the Parties, in each case at the expense of the payor, for value no later than the due date thereof (with twenty four (24) hours advance notice of each wire transfer) to the bank accounts as the payee shall designate in writing within a reasonable period of time prior to such due date.

6.7 RECORDS.

Each Party shall keep and maintain records relating to the subject matter of all reports and payments to be made pursuant to this Article 6 for the U.S. Territory, so that the reports and payments may be verified. Such records shall be open to inspection at any reasonable time within two (2) years after the period to which such records relate, but in any event not more than once per Sales Year, by a nationally recognized independent certified public accountant selected by the inspecting Party, approved by other Party, which approval shall not be unreasonably withheld, and retained at inspecting Party's expense. Said accountant shall sign a confidentiality agreement prepared by the other Party and shall then have the right to examine the records kept pursuant to this Agreement and report to the inspecting Party the findings (but not the underlying data) of said

examination of records as are necessary to evidence that the records were or were not maintained and used in accordance with this Agreement. A copy of any report provided to the inspecting Party by the accountant shall be given concurrently to the other Party. If said examination of records reveals more than five percent (5%) underpayment of the amount payable, expenses for said accountant shall be borne by other Party and the other Party shall promptly pay to the inspecting Party the balance due plus interest calculated at the prime rate of interest as reported in THE WALL STREET JOURNAL for the date of the accountant's report which reveals such underpayment.

6.8 TAXES.

Where any sum due to be paid to a Party under this Article 6 is subject to any withholding or similar tax, the Parties shall use their reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the Party making a payment shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to the other Party, and secure and send to the other Party the best available evidence of such payment.

6.9 NO DOUBLE COUNTING OF COSTS.

For the purpose of determining any cost or expense which is shared by the Parties under this Agreement or otherwise invoiced by one Party to another under this Agreement, any cost or expense allocated by either Party to a particular cost category shall be consistent with the terms of this Agreement and shall not also be allocated to another category. In the event a cost or expense might arguably fall into more than one category, the Parties shall mutually determine which category such cost or expense most appropriately falls into.

ARTICLE 7: INTERNATIONAL TERRITORY

7.1 ACKNOWLEDGEMENT. The Parties recognize that as of the Effective Date, AVI plans to develop and commercialize the Product outside of the United States (the "International Territory"). AVI understands and agrees that SuperGen's right to develop, commercialize, and distribute the Product in the U.S. Territory under this Agreement, shall include the right to collaborate with AVI to develop, commercialize and distribute the Product in the International Territory.

7.2 NOTICE. At least (i) six (6) months prior to AVI commencing development

and/or commercialization of the Product in the International Territory, or (ii) prior to AVI entering into negotiations with a Third Party to develop, commercialize, and/or distribute the Product in the International Territory, AVI shall notify SuperGen in writing of its intent to commence such activities.

7.3 COLLABORATION COMMITTEE. Upon such notice, AVI and SuperGen shall form a International Collaboration Committee to oversee and coordinate a strategy for developing, commercializing and distributing the Product in the International Territory. The International Collaboration Committee shall consist of no more than four (4) total members, with two representatives from each Party.

7.4 DEVELOPMENT AND COMMERCIALIZATION BY AVI AND SUPERGEN. In the event the International Collaboration Committee determines that it is in the best interest of the Parties that AVI and SuperGen develop and commercialize the Product in the International Territory, then:

(a) AVI shall promptly grant to SuperGen the exclusive license and right to develop and distribute the Product in the International Territory; such license and right to be the same as the license and rights granted in Article 2 of this Agreement, except such territory shall be for the International Territory; and

(b) AVI and SuperGen shall negotiate in good faith the terms of such international license agreement, such terms to be no less favorable to SuperGen than those terms contained in this Agreement, except in no event shall SuperGen be obligated to pay any milestones as set forth in Article 5 to develop and distribute such Product.

7.5 DEVELOPMENT AND COMMERCIALIZATION WITH A THIRD PARTY. In the event the International Collaboration Committee determines that it is in the best interest of the Parties that AVI develop and commercialize the Product in the International Territory with a Third Party, then AVI shall be free to enter into a agreement with a Third Party to develop, commercialize, and/or distribute the Product in the International Territory; provided, AVI shall pay to SuperGen a royalty of one-half of all consideration received from such Third Party, including, without limitation:

(a) all consideration in cash and/or equity which AVI or an Affiliate of AVI received from a sublicensee pursuant to the execution of a written license agreement in which AVI grants the sublicensee the right to develop, commercialize, and/or distribute the Product;

(b) all consideration in cash and/or equity which AVI or an Affiliate of AVI received from a sublicensee, which payment is in consideration of development Products reaching a milestone related to the research, development, and/or marketing approval process or sale of such Products; and

(c) all consideration in cash and/or equity which AVI or an Affiliate of AVI received from a sublicensee on the annual net sales of Products sold and/or distributed by such sublicensee, less, actual expenses incurred by AVI in connection with the research, development and/or marketing approval process of such Products in the International Territory, provided, AVI shall first deduct from such expenses any consideration, credit or allowance of any kind received from such Third Party for such expenses incurred by AVI.

The payments due under Sections 7.5(a) and (b) shall be paid to SuperGen within thirty (30) days of the date that AVI receives such payment from its sublicensee. The royalties due pursuant to Section 7.5(c) shall be payable on a country-by-country and Product-by-Product basis, commencing with the first commercial sale of a Product and continuing until (i) the expiration of the last to expire of the patents within the Licensed Patents covering the Product in such country in the International Territory, or (ii) until ten (10) years following the first commercial sale of a Product in such country in the International Territory. Royalty payments shall be made by AVI to SuperGen in United States Dollars within sixty (60) days after the last day of February, May, August, and November for royalties accruing on Net Sales during the three (3) preceding Months. All payments shall be paid by wire transfer or by such other means agreed upon by the Parties, in each case at the expense of AVI, for value no later than the due date thereof (with twenty four (24) hours advance notice of each wire transfer) to the bank accounts as SuperGen shall designate in writing within a reasonable period of time prior to such due date.

ARTICLE 8: PRODUCT MANUFACTURE, SUPPLY AND DISTRIBUTION

8.1 PRODUCT DISTRIBUTION.

(a) AVI shall be responsible for the manufacture, packaging, sterilization and labeling of the Product. SuperGen shall exclusively distribute the Product in the Territory to Third Party customers, including all activities ancillary thereto (including, without limitation, warehousing and shipping).

(b) SuperGen shall use its reasonable efforts to distribute the Product in the Territory to maximize the sales of the Product in the Territory. SuperGen shall keep AVI fully apprised with respect to its distribution. SuperGen shall control all final decisions regarding such distribution activities.

8.2 PRODUCT MANUFACTURE AND SUPPLY.

(a) AVI shall use reasonably diligent efforts to manufacture and supply Product as required by SuperGen. SuperGen shall exclusively obtain from AVI or from its designated Third Party manufacturer(s), and AVI shall exclusively supply to SuperGen (or shall cause or its designated Third Party manufacturer(s) to supply exclusively to SuperGen), SuperGen's requirements for the Product in the U.S. Territory.

(b) SuperGen shall obtain Finished Product for the U.S. Territory from AVI or from its designated Third Party manufacturer(s).

(c) The Parties shall cooperate to determine manufacturing strategy and objectives for the supply of Compound, Product, and Finished Product consistent with the terms of this Agreement, including but not limited to agreeing in writing on the Specifications within 120 days of the Effective Date, and to qualifying a second manufacturer for the Compound, acceptable to both Parties, as soon as possible after the Effective Date.

(d) Within 12 months prior to the agreed projected Launch of the Product in the U.S. Territory, the U.S. Marketing Board shall establish a sales forecast for such Product specifying the Parties' anticipated requirements of the Finished Product in the U.S. Territory for the 18 months commencing approximately 6 months prior to the anticipated date of Launch (the "U.S. Sales Forecast"). The U.S. Marketing Board shall be

responsible for establishing, preparing and updating the U.S. Sales Forecast.

(e) Such Sales Forecasts for the U.S. Territory shall be updated on a quarterly basis so that at the beginning of each calendar quarter, AVI shall have been provided with rolling Sales Forecasts for the twelve (12) month period commencing with the third (3rd) calendar quarter after the date on which such Sales Forecasts are submitted (i.e. approximately 270 days). By way of example only, at the end of the first quarter of a calendar year (assuming the Product has been Launched), the U.S. Marketing Board shall provide AVI with a Sales Forecast of the anticipated requirements of Finished Product for the U.S. Territory for the twelve (12) months consisting of the four quarters of the next calendar year.

8.3 COMMERCIAL SCALE-UP AND DEVELOPMENT

AVI shall exercise its reasonable diligent efforts to pursue the process development of the Product. The Parties shall cooperate to determine the Specifications, process development strategy and objectives for the production of the Compound, the Product, and the Finished Product, consistent with the terms of this Agreement; provided that AVI shall have control of all final decisions regarding process development. AVI shall bear the full costs and expenses of such process development.

8.4 PRODUCT ORDERING AND DELIVERY.

(a) SuperGen shall order Finished Product at the applicable U.S. Transfer Price by means of purchase orders submitted to AVI or AVI's designee at least 90 days in advance of the requested delivery date. Each purchase order shall be governed by the terms of this Agreement and none of the terms or conditions of SuperGen's purchase orders, AVI's acknowledgment forms or any other forms exchanged by the parties shall be applicable, except those, to the extent consistent with the terms set forth herein, specifying quantity ordered, delivery locations and delivery schedule and invoice information.

(b) All orders for delivery during a calendar month that do not exceed one hundred twenty five percent (125%) of the latest Sales Forecast covering such month (excluding any amendments subsequent to the original date of such Sales Forecast) shall be deemed accepted by AVI. AVI shall use its reasonable efforts to supply SuperGen with any Finished Product in excess one hundred twenty five percent (125%) of such Sales Forecast. All other purchase orders must be accepted or rejected by AVI, in writing, by facsimile or air courier, within fifteen (15) business days after receipt from SuperGen. If AVI does not provide such notice of acceptance or rejection within fifteen (15) business days, it shall be deemed to have accepted such purchase orders in full. AVI shall deliver all accepted orders to SuperGen promptly and shall deliver SuperGen's first order for

Finished Product to be sold in the U.S. Territory within thirty (30) days of Regulatory Approval in the U.S. Territory.

(c) All Finished Products shall be delivered to SuperGen's designated destination. Title and risk of loss shall pass from AVI to SuperGen upon acceptance of delivery.

8.5 INVENTORIES AND ALLOCATION.

(a) Subject to the receipt of Finished Product from AVI in accordance with this Article 8, SuperGen shall use its reasonable efforts to maintain adequate inventories of the Finished Product in the Territory to meet the

needs of its customers on a timely basis based upon, among other factors, the Sales Forecast, previous demand histories and seasonal trends, and any customers' contractual commitments. AVI shall use its reasonable efforts to maintain adequate inventories of Finished Product to meet the needs of SuperGen on a timely basis, including but not limited to ensuring that any Third Party manufacturer shall maintain at least 6 months worth of Finished Product in inventory.

(b) In the event that AVI (or its designated Third Party manufacturer(s)) are unable to fill accepted orders for the Finished Product placed by SuperGen pursuant to this Agreement for a total of 60 days, SuperGen may, at its sole discretion, qualify as an additional manufacturer of the Product.

(c) In the event that a visit or report by an authorized agent of a governmental agency in the U.S. Territory, or a visit by an outside independent quality assurance auditor acceptable to both Parties, reveals that AVI's (or AVI's Third-Party manufacturer's) facilities and processes for manufacturing the Compound, the Product or the Finished Product do not comply with applicable laws and regulations, including without limitation Current Good Manufacturing Practices, and if AVI does not rectify the situation to SuperGen's reasonable satisfaction within sixty (60) days of SuperGen's notice to AVI of such situation, then SuperGen may, at its sole discretion, qualify as an additional manufacturer.

(d) In the event that AVI (or its designated Third Party manufacturer(s)) are unable to manufacture the Finished Product to the Product Specifications, SuperGen may, at its sole discretion, qualify as an additional manufacturer of the Product.

8.6 CUSTOMER RELATIONS.

(a) With respect to customer complaints relating to the Promotion or distribution of the Product, SuperGen shall act promptly to remedy such complaints. All Product-related inquiries and Product complaints in the U.S. Territory shall be addressed by SuperGen. Each Party shall keep the other Party fully and promptly apprised of its receipt of any such significant complaints in the U.S. Territory, and provide reasonable cooperation and assistance in dealing with customer complaints.

(b) Any Product warranty to the customers of SuperGen shall run directly from SuperGen to such customers. SuperGen shall not make any warranty or representation to any customers which is more protective of such customers than the warranties and/or representations provided by AVI to SuperGen. For purposes of clarification, the sole remedy of SuperGen customers in the case of defective Product shall be that the Party which sold the defective Product to the customer shall replace such returned defective Product. AVI's Product warranties shall not apply to Product that has been modified or altered in any manner by anyone other than AVI or SuperGen (or their respective Affiliates or subdistributors or sublicensees), or to defects caused (i) through no fault of AVI or SuperGen (or their respective Affiliates or subdistributors or sublicensees), during shipment, (ii) by negligence or misuse on the part of anyone other than AVI or SuperGen (or their respective Affiliates or subdistributors or sublicensees) or (iii) by storage, handling, or usage in any manner inconsistent with the approved Product labeling.

(c) Neither Party shall represent the Product in any manner which is inconsistent with the approved Product labeling or with applicable laws and regulations, or otherwise misrepresent the Product.

8.7 QUALITY CONTROLS.

Both Parties shall institute quality controls in accordance with, and shall comply with, applicable laws and regulations and generally accepted industry standards (including CGMPs as defined below) for the manufacture, storage, shipment, handling and distribution of the Compound, the Product and the Finished Product (as the case may be) and shall define responsibilities for key quality systems and a quality manual agreed to by both Parties (including without limitation, Sample Packs) and shall comply with all applicable laws and regulations relating to the storage, shipment, handling and distribution of the Compound, the Product and the Finished Product. Each Party shall have the right to audit all facilities used by the other Party to fulfill their obligations under this Agreement (including any Third Party manufacturing facilities). For the purposes of this Agreement, "CGMPs" means all applicable standards relating to manufacturing practices for intermediates, bulk products, or finished pharmaceutical products (i) promulgated in the form of laws or regulations by the FDA, or (ii) promulgated by the FDA in the form of guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines) which guidance documents are being implemented within the pharmaceutical manufacturing industry for such products.

8.8 PRODUCT CHARACTERISTICS.

(a) SuperGen shall not be obligated to accept from AVI any Finished Product with less than the greater of (i) seventy-five percent (75%) of approved shelf life for such Finished Product or (ii) thirteen (13) months of remaining shelf life.

(b) AVI shall provide SuperGen with a certificate of analysis with respect to the shipment of the Finished Product to SuperGen. Full batch documentation, including batch production records, and manufacturing and analytical records shall be available for review by SuperGen on site at the manufacturing facility used by AVI (or by AVI's Third Party manufacturer(s)), during regular business hours and upon reasonable advance written notice from SuperGen.

(c) SuperGen shall notify AVI in writing of any defect or shortage in the quantity of any shipment of Finished Product no later than 15 days following receipt of the Finished Product. In the event of any such defect or shortage, AVI shall, at AVI's choice, replace the defective Finished Product or make up the shortage if replacement stock is available in the next shipment of Finished Product, but in any case no later than 30 days or, if no such replacement stock is available, as soon as reasonably practical after receiving such notice, at no additional cost to SuperGen.

(d) With respect to all AVI Third Party manufacturers of the Compound, the Product, and the Finished Product, AVI shall provide SuperGen with a continuing FDA guarantee in the format as set forth in 21 C.F.R. Section 7.13(A)(j).

ARTICLE 9: LICENSE AND PATENT MATTERS

9.1 PATENT PROSECUTION AND MAINTENANCE.

AVI shall maintain the Licensed Patents listed in Exhibit 1, and shall use its reasonable commercial efforts to prosecute any such patent applications included therein, in at least the countries listed on Exhibit 1, and obtain all available patent term extensions. The Parties shall consult together and shall jointly determine patent issues, including but not limited to patenting strategy, prosecution, and response to patent office actions, and SuperGen shall provide such assistance as AVI may reasonably request with respect to such matters.

AVI shall inform SuperGen, on an annual basis and also on SuperGen's written request, about the status of such patent applications and/or patents. AVI shall commit to file additional patent applications claiming the indications listed in Exhibit 1 and as determined to be appropriate in consultation with SuperGen. In the event AVI fails to submit such patent applications, SuperGen shall be entitled to prepare and file such applications on behalf of AVI and shall co-own any such SuperGen filed patents. AVI and SuperGen shall share the cost of such patent applications. In addition, AVI shall have the obligation to file patent applications as deemed appropriate by the Clinical Development Committee on a on-going basis throughout the term of this agreement.

9.2 AVI COVENANTS.

AVI covenants that during the term of this Agreement, it will:

(a) fulfill all of its obligations under the Ohio State University License Agreement or other agreements or other agreements relating to the Product to which AVI is a Party or

becomes a Party during the term of this Agreement (collectively, the "AVI License Agreements"), including, but not limited to, any royalty, milestone or other monetary obligations set forth therein;

(b) take no action nor will it omit to take any action which would cause it to be in breach of any provision of any of the AVI License Agreements relating to the Product which would or could otherwise trigger termination of any such Agreements (e.g., bankruptcy, change of control in whole or with respect to any part of the Territory) or which would or could cause the conversion of any AVI License Agreement from an exclusive to nonexclusive agreement, in whole or with respect to any part of the Territory;

(c) notify SuperGen in the event that, and within 30 days after, AVI receives notice from any of AVI's licensors that AVI is in default under any AVI License Agreement relating to the Product or that any such AVI licensor has terminated or intends to terminate any AVI License Agreement in whole or with respect to any part of the Territory or convert any AVI License Agreement from an exclusive to non-exclusive agreement in whole or with respect to any part of the Territory, or otherwise take any action in connection with a AVI License Agreement which would adversely affect SuperGen's rights under this Agreement. In the event of any default of the type described in this Article 9.2(c), AVI agrees that it will take all reasonable action to correct such defaults;

(d) provide SuperGen with a copy of any reports, correspondence or notice within three (3) business days from the submission to or receipt from Ohio State University under any AVI License Agreement;

(e) notify SuperGen no later than 30 days prior to implementing any decision to abandon or allow to lapse any patent application or patent or not to initiate or take any other patent prosecution activity with respect to any Product Patent, provided that such notification is received by SuperGen no later than 30 days prior to the date upon which an action is required. In such event, AVI agrees that SuperGen may assume any such patent prosecution activity in connection therewith, and AVI shall reasonably cooperate with SuperGen in connection with any such patent prosecution activity and, if requested by SuperGen, shall use its reasonable efforts to seek the cooperation of Ohio State University; and

(f) take no action nor will it omit to take any action which would result in derogation of the Licensed Patents in any existing or future litigation or interference with any Third Parties or future oppositions to foreign

patents of any Third Parties.

9.3 THIRD PARTY INFRINGEMENT.

If SuperGen or AVI become aware of any activity on the part of any Third Party that such Party believes infringes a Valid Claim of a Licensed Patent, such Party shall promptly notify the other Party of all relevant facts and circumstances pertaining to the potential infringement. AVI shall have the right to enforce any rights within the Licensed Patents

against such infringement, at its own cost and expense. SuperGen shall cooperate with AVI in such effort, including but not limited to being joined as a Party to such action, and AVI shall use its reasonable efforts to obtain the cooperation of Ohio State University and any other Third Party licensor in connection with such enforcement.

9.4 SUPERGEN'S RIGHT TO PURSUE THIRD PARTY INFRINGERS.

If AVI shall fail, within 90 days, to either (A) terminate such infringement or (B) institute an action seeking to prevent continuation thereof, and thereafter to diligently prosecute such action, or if AVI sooner notifies SuperGen that it does not plan to terminate the infringement or institute such action, then SuperGen shall have the right to do so at its own expense. AVI, at its own expense, shall cooperate in such effort, including being joined as a Party to such action, and AVI shall use its reasonable efforts to obtain the cooperation of Ohio State University.

9.5 ALLOCATION OF DAMAGE OR SETTLEMENT AMOUNTS.

Any damage award or settlement obtained by a Party enforcing a Licensed Patent pursuant to Article 9.2 or 9.3 above, net of costs incurred, shall be considered as Net Revenue.

ARTICLE 10: ADVERSE EVENTS, RECALLS AND OTHER REGULATORY MATTERS

10.1 ADVERSE REACTION REPORTING. Each Party shall keep the other Party informed of information in or coming into its possession or control concerning side effects, injury, toxicity or sensitivity reaction and incidents of severity thereof associated with commercial and clinical uses, studies, investigations or tests of each Product in the Territory, whether or not determined to be attributable to the Product. SuperGen shall be responsible for filing with the FDA, as required pursuant to 21 C.F.R. Sec. 314.80, any adverse reaction reports that it receives. Within four (4) months of the Effective Date, the respective pharmacovigilance groups of AVI and SuperGen shall enter into a separate agreement covering adverse event information exchange relating to the Product.

10.2 SAFETY ISSUES. In order to ensure that both Parties are provided with an adequate opportunity to review safety matters, the Parties shall mutually agree after the Effective Date on procedures with respect to (i) regulatory reporting requirements, (ii) the review of Product labeling, (iii) maintenance of a safety database and (iv) other safety issues.

10.3 PRODUCT COMPLAINTS AND INQUIRIES.

(a) Any medical or technical Product-related inquiries from consumers, physicians or other Third Party customers who reside in the U.S. Territory shall be handled by SuperGen. Each Party shall prepare and maintain a database containing responses to such inquiries from consumers, physicians or other Third Party customers who reside in the territory for

which it is responsible, and shall make the contents available to the other Party promptly from time to time upon request.

(b) SuperGen shall maintain a record of all complaints or reports of an actual or potential failure of any Product to meet the specifications set forth in regulatory filings or in agreements among the Parties. Such failure may involve the finished Product or one of its intermediate stages. The responsibilities of the Parties with respect to (a) notification of the product complaint from the receiving Party to the other Party and (b) the handling of product complaints shall all be performed in accordance with a procedure to be mutually agreed by the Parties after the Effective Date.

10.4 PRODUCT RECALL. In the event that either Party determines that an event, incident or circumstance has occurred which may result in the need for a recall or other removal of any Product, or any lot or lots thereof, from the market in the Territory, such Party shall advise the other Party and the Parties shall consult with respect thereto. SuperGen shall have the sole authority to decide whether to commence, and the sole responsibility for the handling and disposition of, a recall or other removal of such Product in the U.S. Territory, and SuperGen shall have the sole authority to decide whether to commence. Any such recall or other removal, by either Party, shall occur pursuant to a procedure to be mutually agreed by the Parties after the Effective Date. If a Product (or any lot or lots thereof) is recalled or otherwise removed from the market, the costs and expenses of such recall or removal, including, without limitation, expenses and other costs or obligations to Third Parties, the cost and expense of notifying customers and the costs and expenses associated with shipment of the recalled Product and the cost and expense of destroying the Product removed from the market shall be borne by AVI.

10.5 GOVERNMENTAL CONTACT REPORTING. Each Party shall promptly notify the other Party upon being contacted by the FDA or any other competent governmental authority or agency in the Territory for any material regulatory purpose pertaining to this Agreement or to the Product. Neither Party shall respond to the FDA or such other authority or agency before consulting with the other Party, unless under the circumstances pursuant to which FDA or such other authority or agency contacts such Party, it is not practical or lawful for the contacted Party to give the other Party advance notice, in which event the contacted Party shall inform the other Party of such contact as soon as practical and lawful. In addition, each Party shall keep the other Party advised with respect to information concerning the safety or efficacy of the Product, including but not limited to providing, within three (3) business days of the creation or receipt thereof, all information regarding such safety, efficacy and medical information issues and copies of safety reports filed with the FDA or any other authority or agency.

ARTICLE 11: REPRESENTATIONS AND WARRANTIES

11.1 SuperGen hereby represents to AVI as follows:

(a) SuperGen is a corporation duly organized and validly existing in good standing under the laws of its state of incorporation, with all requisite corporate power and authority to own,

lease and operate its properties and assets and to carry on its business as presently conducted and as proposed to be conducted;

(b) SuperGen has all requisite corporate right, power and authority to enter into this Agreement and the other AVI-SuperGen Agreements and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other AVI-SuperGen Agreements by SuperGen and the consummation by SuperGen of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on SuperGen's behalf. This Agreement and the other AVI-SuperGen Agreements constitute legal, valid and binding obligations of SuperGen, enforceable against SuperGen in accordance with the terms hereof and thereof;

(c) The execution, delivery and performance by SuperGen of this Agreement and each of the other AVI-SuperGen Alliance Agreements and SuperGen's compliance with the terms and provisions hereof and thereof will not, result in any violation of, or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation pursuant to, or a loss of benefits under, any provision of SuperGen's Articles of Incorporation or By-laws, or any mortgage, indenture, lease or other agreement or instrument, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to SuperGen, its properties or assets; and

(d) No consent, approval or authorization of, or designation, declaration or filing with any governmental authority is required in connection with the valid execution, delivery or performance of this Agreement and the other AVI-SuperGen Agreements by SuperGen or the consummation by SuperGen of the transactions contemplated hereby or thereby. Upon their execution and delivery, and assuming the valid execution thereof by AVI, this Agreement and the other AVI-SuperGen Agreements will constitute valid and binding obligations of SuperGen, enforceable against SuperGen in accordance with their respective terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law) and except to the extent that the indemnification agreements of in Article 15 hereof may be legally unenforceable.

11.2 AVI REPRESENTATIONS AND WARRANTIES.

AVI hereby represents and warranties to SuperGen as follows:

(a) AVI is a corporation duly organized and validly existing in good standing under the laws of its state of incorporation, with all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as presently conducted and as proposed to be conducted;

(b) AVI has all requisite corporate right, power and authority to enter into this Agreement and the other AVI-SuperGen Agreements and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other AVI-SuperGen Agreements by AVI and the consummation by AVI of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on AVI's behalf, including but not limited to approval by the stockholders of AVI with respect to the AVI-SuperGen Agreements. This Agreement and the other AVI-SuperGen Agreements constitute legal, valid and binding obligations of AVI, enforceable against AVI in accordance with the terms hereof and thereof;

(c) The execution, delivery and performance by AVI of this Agreement and each

of the other AVI-SuperGen Agreements and AVI's compliance with the terms and provisions hereof and thereof will not result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation pursuant to, or a loss of benefits under, any provision of its Certificate of Incorporation or By-laws, or any mortgage, indenture, lease or other agreement or instrument, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to AVI or AVI's properties or assets;

(d) No consent, approval or authorization of, or designation, declaration or filing with any governmental authority is required in connection with the valid execution, delivery or performance of this Agreement and the other AVI-SuperGen Agreements by AVI or the consummation by AVI of the transactions contemplated hereby or thereby. Upon their execution and delivery, and assuming the valid execution thereof by SuperGen, this Agreement and the other AVI-SuperGen Agreements will constitute valid and binding obligations of AVI, enforceable against AVI in accordance with their respective terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law) and except to the extent that the indemnification agreements of in Article 15 hereof may be legally unenforceable;

(e) to its knowledge and information, as of the Effective Date, there are no patents, trademarks or other proprietary rights which are valid and which would be infringed by making, having made, using, selling, offering for sale or importing the Product in the Territories in accordance with the terms of this Agreement;

(f) as of the Effective Date, AVI is not aware of any compounds or products, the manufacture, use, importation, selling or offering for sale of which would constitute an infringement by a Third Party of the Product Patents;

(g) as of the Effective Date, AVI is aware of no pending interference, opposition proceeding, litigation or any communication which threatens an interference or opposition proceeding

or litigation before any patent and trademark office, court, or any other competent entity in any jurisdiction in regard to the Product Patents;

(h) as of the Effective Date, AVI has disclosed to SuperGen all protocols, data (including but not limited to preclinical and clinical data), reports, and other information and materials regarding the Compound and the Product;

(i) as of the Effective Date, AVI has provided to SuperGen a complete and accurate copy of each of the AVI license agreements with respect to the Product;

(j) as of the Effective Date, there are no material facts which AVI has not disclosed to SuperGen regarding the manufacture, use or sale of any Product or the practice of any inventions included in the Product Patents or the use of the Product Technology by SuperGen, including without limitation any material facts regarding the possibility that such manufacture, use, sale or practice might infringe any Third Party's know-how, patent rights or other intellectual property in the Territory;

(k) at no time during the term of this Agreement shall AVI enter into any transaction providing for debt financing which by its terms (A) imposes a lien, license, security interest or other encumbrance upon or (B)

transfers any of the AVI Technology relating to the Compound or the Product;

(l) with respect to the Compound, (A) AVI has obtained and is in substantial compliance with all applicable regulatory approvals, applications, licenses, requests for exemption, permits or other regulatory authorizations with the FDA, or any state or local regulatory body necessary to conduct its business activities to date; and (B) to the extent the Compound is intended for export from the United States, and to the extent applicable, AVI is in compliance in all material respects with either all FDA requirements for marketing or as set forth in 21 U.S.C. Section 381(e) or 382;

(m) to the knowledge and information of AVI, all manufacturing operations performed by or on behalf of AVI for the Compound and/or the Product have been and are being conducted in substantial compliance with the current good manufacturing practices issued by the FDA and all other relevant governmental authorities or agencies, to the extent applicable;

(n) to the knowledge and information of AVI, all nonclinical laboratory studies, as described in 21 C.F.R. Article 58.3(d), sponsored by AVI for the Compound and/or the Product have been and are being conducted in substantial compliance with the good laboratory practice regulations set forth in C.F.R. Part 58 and similar regulations of all other relevant governmental authorities or agencies, to the extent applicable; and

(o) Finished Product supplied to SuperGen by AVI under this Agreement shall conform to the Specifications applicable thereto and shall be manufactured in compliance with

applicable CGMPs and other applicable laws and regulations in the Territories, and Compound and Product used in Finished Product supplied to SuperGen by AVI under this Agreement shall conform to the Specifications applicable thereto and shall be manufactured in compliance with applicable CGMPs and other applicable laws and regulations in the Territory.

11.3 LIMITATION ON WARRANTIES. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY MAKES NO OTHER WARRANTIES OR REPRESENTATIONS, INCLUDING FITNESS FOR PURPOSE INTENDED OR MERCHANTABILITY, WHETHER EXPRESS OR IMPLIED.

ARTICLE 12: LIMITATION ON LIABILITY

EXCEPT AS OTHERWISE PROVIDED, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL ARISING OUT OF OR RELATING TO THIS AGREEMENT; PROVIDED HOWEVER, THIS LIMITATION SHALL NOT APPLY TO LOSSES ARISING FROM THIRD PARTY CLAIMS FOR WHICH A PARTY IS INDEMNIFIED UNDER THE TERMS OF THIS AGREEMENT.

ARTICLE 13: CONFIDENTIALITY AND NONDISCLOSURE

13.1 CONFIDENTIALITY OBLIGATION.

Each of SuperGen and AVI (the "Receiving Party") shall keep strictly confidential any information disclosed in writing, orally, visually or in any other manner by the other Party (the "Disclosing Party") or otherwise made available to the Receiving Party which the Disclosing Party considers to be and treats as proprietary or confidential ("Confidential Information"). Without limiting the generality of the foregoing, all proprietary information concerning the Disclosing Party's business, operations, suppliers, products, product manufacture, sale, marketing or distribution, trade secrets and intellectual property shall be considered

Confidential Information by the Receiving Party. Any data or other information relating to or resulting from the clinical trials of the Product shall be deemed to be Confidential Information of both Parties. The Disclosing Party shall use commercially reasonable efforts to designate any written Confidential Information disclosed to the other Party as Confidential Information by prominently marking it "confidential," provided that the failure to so mark shall not exclude such written information from the provisions of this Article 13. "Confidential Information" shall not include information:

(a) which is or becomes generally available to the public other than as a result of unauthorized disclosure thereof by the Receiving Party;

(b) which is lawfully received by the Receiving Party on a nonconfidential basis from a Third Party that is not itself under any obligation of confidentiality or nondisclosure to the Disclosing Party or any other Person with respect to such information;

(c) which by written evidence can be shown by the Receiving Party to have been independently developed by or for the Receiving Party;

(d) which the Receiving Party establishes by competent proof was in its possession at the time of disclosure by the other Party and was not acquired, directly or indirectly from the other Party under any obligation of confidentiality;

(e) which was independently developed by the Receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development.

All information, data and other materials disclosed by one Party to the other pursuant to the Confidentiality Agreement, dated April 4, 2000, shall be deemed to have been disclosed by the disclosing Party under this Agreement.

13.2 NONDISCLOSURE OF CONFIDENTIAL INFORMATION.

The Receiving Party shall use Confidential Information solely for the purposes of this Agreement and shall not disclose or disseminate any Confidential Information to any Third Party at any time without the Disclosing Party's prior written consent, except for disclosure to those of its directors, officers, employees, accountants, attorneys, advisers, permitted sublicensees, agents and representatives whose duties reasonably require them to have access to such Confidential Information, provided that such directors, officers, employees, accountants, attorneys, advisers, agents and representatives are required to use the Confidential Information solely for purposes of this Agreement and maintain the confidentiality of such Confidential Information to the same extent as if they were Parties hereto.

13.3 EXCEPTION.

The foregoing confidentiality and nondisclosure obligations shall not apply to information which is required to be disclosed by law or by regulation; provided, that (i) the Receiving Party gives the Disclosing Party reasonable advance notice of the disclosure, to the extent reasonably practicable and legally permissible; (ii) the Receiving Party uses reasonable efforts to resist disclosing the Confidential Information; (iii) the Receiving Party reasonably cooperates with the Disclosing Party on request to obtain a protective order or otherwise limit the disclosure; and (iv) upon the reasonable request of the Disclosing Party, the Receiving Party shall provide a letter from its

counsel confirming that the Confidential information is, in fact, required to be disclosed.

13.4 INJUNCTIVE RELIEF.

The Parties acknowledge that either Party's breach of this Article 13 may cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the

event of a breach, the non-breaching Party shall be entitled to injunctive relief in addition to any other remedies it may have at law or in equity.

13.5 SURVIVAL.

The confidentiality and nondisclosure obligations of this Article 13 shall survive the expiration or termination of this Agreement and remain in effect for a period of five (5) years following the expiration or termination of this Agreement.

ARTICLE 14: TRADEMARKS

14.1 AVI TRADEMARKS.

AVI shall be solely responsible for the selection, filing, registration and maintenance of the AVI Trademark(s) in the U.S. Territory.

14.2 LIMITED TRADEMARK LICENSE.

Subject to the terms of this Agreement, AVI hereby grants to SuperGen (i) a nonexclusive limited license in the Territory to use AVI's name and logo, and (ii) a coexclusive limited license in the U.S. Territory to use the AVI Trademark(s), in each instance solely for the purpose of promoting distributing and selling the Product in the Territory in accordance with the terms and conditions of this Agreement.

14.3 SUPERGEN TRADEMARK(S).

SuperGen shall be solely responsible for the selection, filing, registration and maintenance of the SuperGen Trademark(s). SuperGen shall keep AVI fully apprised with respect to the its trademark activities and shall consult with AVI regarding the selection of the SuperGen Trademark(s). SuperGen shall control all final decisions regarding the SuperGen Trademarks.

14.4 USE OF TRADE NAMES AND LOGOS.

Each Party recognizes that the name and logo of each of the Parties represents a valuable asset of such entity and that substantial recognition and goodwill are associated with each Party's name, and logo. Each Party hereby agrees that, without prior written authorization of the other Party, it shall not use the name or logo of the other Party for any purpose other than the promotion, distribution and sale of the Product solely to the extent required to fulfill its obligations under this Agreement. In addition, AVI shall only use the SuperGen name and logo in the form, manner and logotype approved in writing by SuperGen, and SuperGen shall only use the AVI name and logo and the AVI Trademarks in the form, manner and logotype approved in writing by AVI. Except for the limited license granted in Article 14.2 above, nothing in this Agreement shall be construed as an assignment by AVI to SuperGen of any right, title or interest in or to the AVI name or

logo or the AVI Trademarks, or an assignment by SuperGen to AVI of any right, title or interest in or to the SuperGen name or logo or the SuperGen Trademarks; it being understood that all right, title and interest (including the goodwill associated therewith) in and to the AVI name and logo and the AVI Trademark(s) is expressly reserved by AVI, and all right, title and interest (including the goodwill associated therewith) in and to the SuperGen name and logo and the SuperGen Trademarks is expressly reserved by SuperGen.

14.5 INJUNCTIVE RELIEF.

Each Party acknowledges that a violation of this Article 14 would cause irreparable harm to the other Party for which no adequate remedy at law exists, and each Party therefore agrees that, in addition to any other remedies available, and notwithstanding any other provision in this Agreement, the aggrieved Party shall be entitled to injunctive relief to enforce the terms of this Article 14. If either Party prevails in any such action, it shall be entitled to recover all costs and expenses, including reasonable attorney's and other professional fees and expenses incurred because of any legal action arising in relation to this Article 14.

14.6 NOTIFICATION OF INFRINGEMENT AND ENFORCEMENT.

Each Party shall notify the other Party of any infringement or misuse of SuperGen's and AVI's Trademark(s) of which such Party becomes aware. Each party shall be solely responsible to prosecute any infringement of the its Trademark(s).

ARTICLE 15: INDEMNIFICATION

15.1 INDEMNIFICATION BY AVI.

Except as may be otherwise provided herein, AVI shall defend, indemnify and hold SuperGen, all of its directors, officers and employees, and SuperGen Sales Representatives (collectively the "SuperGen Indemnitees") harmless from and against all Losses incurred in connection with any Third Party suits, claims or causes of action arising out of or resulting from:

(a) AVI's breach of any representation, warranty, covenant, or obligation provided for in this Agreement;

(b) an infringement claim arising from SuperGen's use of the AVI name or logo or a AVI Trademark in connection with the promotion or sale of the Products, provided SuperGen's use is in compliance with the terms of this Agreement;

(c) the negligence, recklessness or willful misconduct of AVI and its directors, officers or employees or AVI Sales Representatives;

(d) any patent infringement claim arising from the manufacture, importation, use or sale of the Product;

(e) any product liability claim arising from the development or manufacture of the Product.

15.2 INDEMNIFICATION BY SUPERGEN.

Except as may be otherwise provided herein, SuperGen shall defend, indemnify and hold AVI, its directors, officers and employees, and AVI Sales Representatives (collectively the "AVI Indemnitees") harmless from and against all Losses incurred in connection with any Third Party suits, claims or causes of action arising out of or resulting from:

(a) SuperGen's breach of any representation, warranty, covenant, or obligation provided for in this Agreement;

(b) an infringement claim arising from AVI's use of the SuperGen name or logo in connection with the promotion or sale of the Product, provided AVI's use is in compliance with the terms of this Agreement;

(c) the negligence, recklessness or willful misconduct of SuperGen, its directors, officers or employees or SuperGen Sales Representatives, including, but not limited to, product liability claims arising out of off-label promotions by SuperGen, its Affiliates, their directors, officers or employees, or SuperGen Sales Representatives; or

(d) any patent infringement claim arising from SuperGen's or its Affiliates' or permitted sublicensee's utilization of process technology for the manufacture of the Product which has not been approved by AVI.

15.3 INDEMNIFICATION PROCEDURE.

Any SuperGen Indemnitee or AVI Indemnitee, as the case may be, shall notify AVI or SuperGen (the "Indemnifying Party") promptly in writing of an indemnifiable claim or cause of action under Article 15.1 or 15.2 upon receiving notice or being informed of the existence thereof. The Indemnifying Party shall assume, at its cost and expense, the sole defense of such claim or cause of action through counsel selected by the Indemnifying Party and reasonably acceptable to the other Party. The Indemnifying Party shall maintain control of such defense, including any decision as to settlement; provided that:

(a) the Indemnifying Party shall not enter into any binding settlement, consent to any judgment, or otherwise resolve any such claim or action pursuant to which the other Party would be obligated to take or refrain from taking any action (including but not limited to being enjoined from making, using, importing, selling or offering to sell the Product) or to make any payments or admissions, without the other Party's prior written consent; and

(b) in the event that the Indemnifying Party does not diligently defend such claim or cause of action on a timely basis, then, without prejudice to any other rights and remedies available to the other Party under this Agreement, the other Party may take over such defense with counsel of its choosing at the Indemnifying Party's cost and expense.

(c) The other Party may, at its option and expense, participate in the Indemnifying Party's defense, and if the other Party so participates, the Parties shall cooperate with one another in such defense. The Indemnifying Party shall bear the total costs of any court award or settlement of such claim or cause of action and all other costs, fees and expenses related to the resolution thereof (including reasonable attorney's and other professional fees and expenses except for attorneys' fees for which the other Party is responsible in the event that the other Party participates in the Indemnifying Party's defense of such claim or cause of action). The indemnification obligations herein shall apply on a first dollar basis without limitation or reduction due to any deductible or self-insured retention which AVI or SuperGen respectively may have under their respective insurance coverage.

15.4 PRODUCT LIABILITY. In the event of a product liability claim with respect to the Product which is not covered by the foregoing indemnity provisions in this Article 15, the Parties shall work together to resolve the claim. SuperGen shall maintain control of the defense of any such product liability claim with respect to the U.S. Territory.

ARTICLE 16: TERM AND TERMINATION

16.1 TERM.

(a) The term of this Agreement shall commence on the Effective Date and, unless terminated sooner in accordance with this Article 16 the term of this Agreement, shall expire upon the earlier of (i) the date upon which a generic version of the Product is first sold in the U.S. by someone other than SuperGen or (ii) the date which is fifteen (15) years after the date of Regulatory Approval of the Product in the U.S., provided that the Parties may renew this Agreement for the U.S. for (i) further successive one (1) year periods, or (ii) further successive periods of time during which any applicable marketing exclusivity precludes the effective approval by the FDA of any product containing the Compound, upon written agreement made no later than thirty (30) days prior to the end of the original term and any succeeding extensions thereof.

16.2 TERMINATION FOR MATERIAL BREACH.

Either party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, upon sixty (60) days' written notice in the event that the other party breaches a material provision of this Agreement and fails to cure such breach within sixty (60) days of notice of the breach.

16.3 TERMINATION FOR NON-APPROVAL OR LACK OF COMMERCIAL VIABILITY.

Commencing after receiving the completed Phase III data, SuperGen may terminate this Agreement at any time, upon thirty (30) days written notice to AVI, if: (i) the product is not deemed by SuperGen to qualify for NDA acceptance, or (ii) SuperGen, in the exercise of its reasonable commercial judgment, has determined that the Product and/or the

material terms and conditions of this Agreement are not commercially viable.

16.4 BANKRUPTCY OR INSOLVENCY. Either Party may, in addition to any other remedies available to it by law or in equity, terminate this Agreement, upon thirty (30) days' written notice to the other Party in the event the other Party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the other Party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the other Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereinafter in effect (an "Insolvency Event"). However, in the event that AVI experiences an Insolvency Event and any trustee acting on behalf of AVI or its debtors rejects this Agreement, SuperGen shall have the right to elect to retain its rights under this Agreement upon written notification to said trustee of its intentions to do so. All rights and licenses granted hereunder are, for all purposes of this Agreement, licenses of rights to intellectual property and may not be terminated upon an Insolvency Event

without the express agreement of the Party that is not insolvent. Notwithstanding anything to the contrary in this Agreement, in the event that AVI experiences an Insolvency Event and SuperGen does not elect to terminate this Agreement, then SuperGen shall automatically have the right to make, in its sole discretion, any decisions relating to the clinical development of the Product, regulatory strategies and tactics for the Product, and the marketing, promotion and sale of the Product which decisions were heretofore to be made either jointly by the Parties or solely by AVI under this Agreement.

16.5 SERIOUS EVENTS.

Should there occur serious and unexpected events which, from a reasonable pharmaceutical company's point of view, would make it impossible or impracticable to pursue the commercialization of the Product, either Party may terminate this Agreement upon thirty (30) days' written notice.

16.6 CHANGE OF CONTROL OR OWNERSHIP.

Either Party may terminate this Agreement upon thirty (30) days' written notice if the ownership or control of at least 50% of the assets or voting securities of the other Party are transferred and, in the non-changing Party's reasonable judgement, the other Party's new owner or controlling entity is a competitor of the non-changing Party in the field of oncology.

16.7 EFFECT OF TERMINATION.

(a) If this Agreement is terminated under this Article 16, the termination Party shall have the right to terminate the Common Stock and Warrant Purchase Agreement, to the extent that there are any continuing obligations thereunder upon thirty (30) days written notice, in its

sole discretion and in addition to any other rights and remedies which may be available at law or in equity or under the terms of the AVI-SuperGen Agreements set forth above.

(b) PHASE-OUT PERIOD.

Within thirty (30) days of the expiration or termination of this Agreement under this Article 15, SuperGen may continue to fill all outstanding orders for the Product and SuperGen shall refer any new orders for the Product to AVI. During the Phase-Out Period, SuperGen shall not be required to perform any Details for the Product and SuperGen shall receive its share of the U.S. Product Profits, unless SuperGen was terminated hereunder for its material breach of this Agreement. SuperGen shall promptly return all Promotional Materials and Sample Packs for the terminated Product to AVI and shall delete the Product from its catalogues and price lists as soon as reasonably practical. In the event of any problems relating to the Product or customer relations issue during the Phase-Out Period, SuperGen shall cooperate fully with AVI to ensure customer satisfaction and compliance with all applicable laws and regulations.

(c) POST-TERMINATION ORDERS.

After expiration or termination of this Agreement the placement of any order for Product by SuperGen to AVI, and the acceptance of any order from, or sale of any Product to SuperGen by AVI, shall not be construed as a renewal or extension of this Agreement nor as a waiver or reversal of termination of this Agreement.

16.8 SURVIVAL.

Other than obligations which have accrued and are outstanding as of the date of any expiration or termination of this Agreement, all rights granted and obligations undertaken by the Parties hereunder shall terminate immediately upon the termination or expiration of this Agreement; except for the following which shall survive according to their terms:

(a) The limitations on liability of Article 12;

(b) The confidentiality and nondisclosure obligations of Article 13;

(c) The indemnification obligations of Article 15 with respect to claims that arise from events occurring prior to termination or expiration of the Agreement;

(d) The effect of termination, survival, and nonexclusive rights and remedies clauses of Article 16.7, 16.8 and 16.9;

(e) The insurance obligations of Article 18; and

(f) The miscellaneous obligations of Article 20.

16.9 NONEXCLUSIVE RIGHTS AND REMEDIES.

Except as otherwise set forth in this Agreement, all rights and remedies of the Parties provided under this Agreement are not exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.

16.10 CONDITIONS TO EFFECTIVENESS.

The Effective Date shall be the date on which the following conditions have been satisfied, as confirmed by both Parties in writing:

(a) No order, statute, rule, regulation, executive order, injunction, stay, decree or restraining order shall have been enacted, entered, promulgated or enforced by any court of competent jurisdiction or governmental or regulatory authority that prohibits the execution, delivery or performance of any of the AVI-SuperGen Agreements, and no proceeding by any governmental or regulatory authority or instrumentality shall be pending or threatened, which seeks to prohibit or declare illegal the execution, delivery or performance of any of the AVI-SuperGen Agreements;

(b) All corporate and other proceedings taken or to be taken in conjunction with the transactions in the AVI-SuperGen Agreements, and all documents incident thereto, shall be reasonably satisfactory in form and substance to SuperGen and to AVI, respectively;

(c) AVI shall have obtained the consents and/or approvals identified in Article 11.2 and SuperGen shall have received from AVI a copy of the executed consents and/or approvals identified in Article 11.2 and a certificate signed by an appropriate officer of AVI as to AVI's compliance with the conditions set forth in this Article 16.10;

(d) The representations and warranties of AVI contained herein and in the other AVI-SuperGen Agreements shall be true and correct at and as of the Effective Date as though restated on and as of the Effective Date; and

(e) AVI shall have received from SuperGen a certificate signed by an appropriate officer as to SuperGen's compliance with this Article 16.10.

16.11 NON-FULFILLMENT OF CONDITIONS. The non-fulfillment of any of the conditions described in Article 16 above (whether or not the Effective Date occurs) shall not result in any liability to any Party unless such non-fulfillment is a result of a breach of this Agreement or any of the other AVI-SuperGen Agreements by such Party.

ARTICLE 17: TRANSFER OF TECHNOLOGY

17.1 TRANSFER BY AVI.

Within thirty (30) days following the Effective Date and as far as it has not previously done so, AVI shall supply SuperGen with all AVI Technology necessary for the manufacture, use and sale of the Product in AVI's possession or control (including but

not limited to technical information reasonably required by SuperGen for regulatory, marketing and sales purposes under this Agreement). With respect to any AVI Technology subsequently developed or obtained by AVI during the term of this Agreement, such disclosure will be made to SuperGen at least on a monthly basis or sooner, if practicable.

17.2 TECHNICAL ASSISTANCE. Solely for the purpose of enabling SuperGen to exercise its rights pursuant to Article 8.5 above, AVI shall, upon request by SuperGen, provide SuperGen with reasonable cooperation and assistance, consistent with the other provisions hereof, in connection with the transfer of AVI Technology. Such assistance may include, but is not limited to, development of the formulations of the Product; procurement of supplies and raw materials; initial development and production batch manufacturing runs; process, specification and analytical methodology design and improvement; and, in general, such other reasonable assistance as may contribute to the efficient application by SuperGen of the Product Technology. In this regard, AVI agrees to make appropriate employees of AVI reasonably available to assist SuperGen, and AVI agrees to provide reasonable numbers of appropriate SuperGen personnel with access during normal business hours to the appropriate personnel and operations of AVI for such periods of time as may be reasonable in order to familiarize SuperGen personnel with the AVI Technology as applied by AVI. At SuperGen's reasonable request, such assistance shall be furnished at SuperGen's or its subcontractors' or permitted sublicensees' facilities in the Territory, subject to a mutually agreed upon schedule. Such technical assistance shall include but not be limited to the following:

(a) AVI shall: (i) provide SuperGen with a written right of reference to any and all Drug Master File(s) ("DMF") relating to the manufacture of the Compounds existing during the term of this Agreement; and (ii) reasonably cooperate with SuperGen in obtaining access to and letters of authorization to refer to the DMF's of AVI's subcontractors or Third Party manufacturer(s) which are, or will be, supplying any Compound or Product; and

(b) Within forty five (45) days after the Effective Date, AVI shall provide SuperGen with copies of all documentation in AVI's possession or control, including all correspondence between AVI and its subcontractors and/or Third Party manufacturer(s), regarding the manufacture of the Compound and the Product which would be necessary or useful to assist SuperGen in the commercial production of the Compound or Product.

17.3 LANGUAGE OF DISCLOSURES.

All disclosure pursuant to this Agreement will be in English.

ARTICLE 18: INSURANCE

Beginning on the Effective Date and until the date which is one day prior to the date of initial Launch, SuperGen and AVI shall maintain product liability insurance with an A.M. Best Company rating of at least A+ with a minimum annual amount of: (i) Five Million Dollars

($5,000,000) per occurrence, and (ii) Ten Million Dollars ($10,000,000) aggregate. Beginning on the date of initial Launch and for a period of five (5) years after termination of this Agreement, SuperGen shall maintain product liability insurance with an A.M. Best Company rating of at least A+, with minimum annual amounts per occurrence and in the aggregate which are adequate to SuperGen's reasonable satisfaction.

ARTICLE 19: FORCE MAJEURE

If any circumstance beyond the reasonable control of either Party occurs which delays or renders impossible the performance of certain of that Party's obligations under this Agreement on the dates herein provided ("Force Majeure"), such obligations shall be postponed for such time as such performance necessarily has had to be suspended or delayed on account thereof, provided such Party shall notify the other Party in writing as soon as practicable, but in no event more than ten (10) business days after the occurrence of such event of Force Majeure, which notice shall reasonably attempt to identify such obligations under this Agreement and the extent to which performance thereof will be affected. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such event, provided that such Party who fails because of an event of Force Majeure to perform its obligations hereunder shall upon the cessation of the Force Majeure event take all reasonable steps within its power to resume with the least possible delay compliance with its obligations. Events of Force Majeure shall include, without limitation, war, revolution, invasion. insurrection, riots, mob violence, sabotage or other civil disorders, acts of God, limitations imposed by exchange control regulations or foreign investment regulations or similar regulations, laws, regulations or rules of any government or governmental agency, any inordinate and unanticipated delays in the regulatory review or governmental approval process that are within the sole control of such government or governmental agency, any delay or failure in manufacture, production or supply by Third Parties of any goods or services, any withdrawal or recall of a Product at the direction of any governmental authority and any failure of a computer system.

ARTICLE 20: MISCELLANEOUS

20.1 RELATIONSHIP OF THE PARTIES.

Each of the Parties shall be furnishing its services hereunder as an independent contractor, and nothing herein shall create any association, partnership or joint venture between the Parties or any employer-employee or agency relationship. No agent, employee or servant of either Party shall be or shall be deemed to be the employee, agent or servant of the other Party, and each Party shall be solely and entirely responsible for its acts and the acts of its employees.

20.2 RELATIONSHIP WITH AFFILIATES.

Unless the context otherwise indicates or as set forth in this Article 20.2, (i) any reference to a Party herein shall include the Affiliates of

such Party, with the following exceptions: (A) the appointment of exclusive distributorship pursuant to Article 2.1; (B) the grant of license to sell the Product pursuant to Article 2.5; (C) the grant of right with respect to additional products pursuant to Article 2.6; and (D) the right with respect to patent prosecution and infringement pursuant to Article 9; and (ii) each Party may utilize the services of its Affiliates to perform services, activities and/or obligations permitted or required under this Agreement to the same extent as if such Affiliate were a Party to this Agreement; provided that any such services, activities or obligations under this Agreement permitted or required to be performed by such Party relating to the U.S. Territory will be performed only by such Party or a wholly-owned U.S. subsidiary of such Party. Any Affiliates so utilized shall be subject to all the terms and conditions applicable to such Party under this Agreement, including but not limited to provisions establishing standards for performance.

20.3 DISPUTE RESOLUTION.

The Parties agree that any dispute that arises in connection with this Agreement shall first be presented to the respective presidents of AVI and SuperGen, or their designees, for resolution. If no resolution is reached, then such dispute shall be resolved by binding Alternative Dispute Resolution ("ADR") in the manner described in Exhibit 2.

20.4 COUNTERPARTS. The Agreement may be executed simultaneously in any number of counterparts and may be executed by facsimile. All counterparts shall collectively constitute one and the same Agreement.

20.5 NOTICES. In any case where any notice or other communication is required or permitted to be given hereunder, such notice or communication shall be in writing, and sent by overnight express, facsimile or registered or certified mail (with return receipt requested) and shall be sent to the following address (or such other address as either Party may designate from time to time in writing):

IF TO SUPERGEN, INC
SuperGen, Inc
Two Annabel Lane, Suite 220
San Ramon, CA 94583
Telefax: (925) 327-7347
Attention: Dr. Joseph Rubinfeld
Chief Executive Officer and President

Copy to:
Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304-1050

IF TO AVI BIOPHARMA INC
AVI BioPharma,Inc
One SW Columbia, Suite 1105
Portland OR 97258
Telefax: (503) 227-0751
Attention: Dr. Denis Burger
President and Chief Executive Officer

Copy to:
Ater Wynne LLC
222 SW Columbia, #1700
Portland, Oregon 97201
Attention: Byron Milstead

20.6 BINDING EFFECT; ASSIGNMENT.

This Agreement may not be assigned, in whole or in part, by either Party without the prior written consent of the other Party, and any attempted assignment without such consent shall be null and void; provided that no prior written consent shall be required in the event that a Third Party acquires substantially all of the assets or outstanding shares of, or merges with, the assigning Party to which this Agreement pertains. No assignment of this Agreement or of any rights hereunder shall relieve the assigning Party of any of its obligations or liability hereunder. This Agreement shall inure to the benefit of and be binding upon each of the Parties hereto and their respective successors and permitted assigns.

20.7 ENTIRE AGREEMENT.

The terms and conditions contained herein and in the other AVI-SuperGen Agreements constitute the entire agreement between the Parties relating to the subject matter of hereof and thereof and shall supersede all previous communications and/ or agreements between the Parties with respect to the subject matter hereof and thereof, respectively. Neither Party has entered into this Agreement in reliance upon any representation, warranty, covenant or undertaking of the other Party that is not set out or referred to in this Agreement.

20.8 AMENDMENT.

The Agreement may be varied, amended or extended only by the written agreement of the Parties through their duly authorized officers or representatives, specifically referring to this Agreement.

20.9 SEVERABILITY.

In case any one or more of the provisions contained herein shall, for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such invalid, illegal or unenforceable provision or provisions had never been contained herein unless the deletion of such provision or provisions would result in such a material change as to cause completion of the transactions contemplated herein to be impossible and provided that the performance required by this Agreement with such clause deleted remains substantially consistent with the intent of the Parties.

20.10 COMPANY EMPLOYEES.

Each Party shall not directly or indirectly solicit for employment, any employee of the other Party who has been directly involved in the performance of this Agreement during the term of this Agreement. It shall not be a violation of this provision if any employee responds to a Party's general advertisement of an open position.

20.11 PUBLICITY.

Except as otherwise provided herein, each Party shall maintain the confidentiality of all provisions of this Agreement and this Agreement itself and, without the prior written consent of both Parties, neither Party shall make any press release or other public announcement of or otherwise disclose to any Third Party this Agreement or any of its provisions or anything relating to the Compound, the Product or the Finished Product, except for: (i) for disclosure to those of its directors, officers, employees, accountants, attorneys, advisers and agents whose duties reasonably require them to have access to the Agreement, provided that such directors, officers, employees,

accountants, attorneys, advisers, and agents are required to maintain the confidentiality of the Agreement to the same extent as if they were Parties hereto, (ii) such disclosures as may be required by applicable laws and regulations, in which case the disclosing Party shall provide the nondisclosing Party with at least five (5) business days prior written notice of such disclosure so that the nondisclosing Party shall have the opportunity if it so desires to seek a protective order or other appropriate remedy and, in connection with any such required disclosure, the disclosing Party shall use reasonable efforts to obtain confidential treatment for such disclosure and/ or to prevent or modify such disclosure as may be requested by the nondisclosing Party (to the extent permitted by applicable law and regulation); and (iii) such disclosure as contained in the press releases mutually approved by the Parties immediately following the execution of this Agreement. Once published in a press release, either Party may mention the fact of this Agreement and previously disclosed details of this Agreement in further press releases without the prior written approval of the other Party.

20.12 APPLICABLE LAW.

The Agreement shall be governed by the laws of the State of Delaware applicable to contracts made and to be performed entirely within such jurisdiction and without giving effect to its choice or conflict of laws rules or principles. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to reasonable attorneys' fees, costs and necessary disbursements, in addition to any other relief to which the Party may be entitled.

20.13 HEADINGS.

The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect the meaning or interpretation of this Agreement.

20.14 INTERPRETATION.

(a) Wherever any provision of this Agreement uses the term "including" (or "includes"), such term shall be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitation" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes").

(b) Wherever any provision of this Agreement provides that a Party's consent shall not be unreasonably withheld, such provision shall be deemed to provide that such consent shall in addition not be unreasonably delayed.

(c) The recitals set forth at the start of this Agreement, along with the Exhibits to this Agreement, and the terms and conditions incorporated in such recitals and Exhibits shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and Exhibits and the terms and conditions incorporated in such recitals and Exhibits.

(d) In the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern.

(e) Unless otherwise explicitly stated, in the event of any conflict between the terms of this Agreement and the terms and conditions of any of the Exhibits hereto, the terms of this Agreement shall prevail.

(f) The Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter.

(g) Unless otherwise provided, all references to Sections, Articles and Exhibits this Agreement are to Sections, Articles and Exhibits of and to this Agreement.

20.15 NO WAIVER OF RIGHTS.

No failure or delay on the part of either Party in the exercise of any power or right hereunder shall operate as a waiver thereof. No single or partial exercise of any right or power hereunder shall operate as a waiver of such right or of any other right or power. The waiver by either Party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any other or subsequent breach hereunder.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the date first written above.

AVI BIOPHARMA, INC.	SUPERGEN, INC
By: /s/ Denis R. Burger	By: /s/ Dr. Joseph Rubinfeld
Name: Denis R. Burger, Ph.D.	Name: Dr. Joseph Rubinfeld
Title: President, CEO	Title: President, CEO

EXHIBIT 1

PATENTS

[LIST OF (i) LICENSED PATENTS, (ii) COUNTRIES IN WHICH LICENSED PATENTS TO BE PROSECUTED, AND (iii) ADDITIONAL INDICATIONS IN WHICH AVI IS TO COMMIT TO FILE ADDITIONAL PATENT APPLICATIONS, TO BE ATTACHED HERE.]

EXHIBIT 2

DISPUTE RESOLUTION (SUPERGEN TO WRITE THIS)

[TO BE ATTACHED HERE]

QuickLinks -- Click here to rapidly navigate through this document

EXHIBIT 23

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As Independent public accountants, we hereby consent to the incorporation of our report dated February 7, 2001, included in this Form 10-K into the Company's previously filed Registration Statement No. 333-34047 on Form S-8.

ARTHUR ANDERSEN LLP

Portland, Oregon,
March 27, 2001

QuickLinks

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS