

# FAVRILLE

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Cancer treatment – We make it personal™

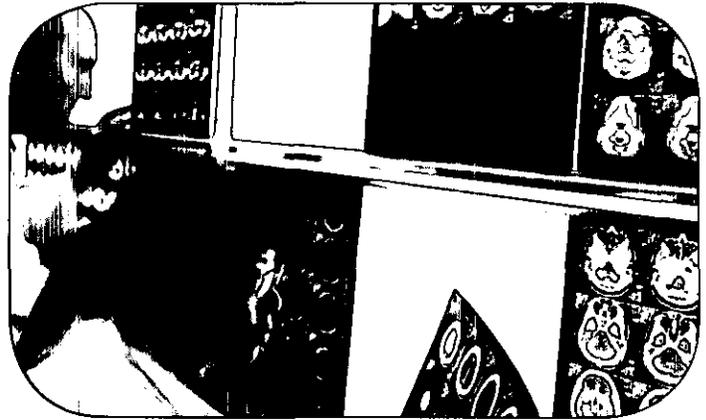


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2006 Annual Report

## Growing market— A complement to Rituxan®

Our pivotal Phase 3 clinical trial is designed to evaluate Favld's ability to extend TTP in patients with follicular B-cell NHL following treatment with Rituxan, the current standard of care. Annual sales of Rituxan in the U.S. have grown from \$162 million in 1998 to more than \$2 billion in 2006.



## Phase 3—Our pivotal trial



We initiated our placebo-controlled, double-blind, pivotal Phase 3 clinical trial of Favld in patients with follicular B-cell NHL in July 2004 and completed patient enrollment 18 months later with 349 patients randomized into the trial. Analysis of our primary endpoint in the trial, TTP, is event-driven and currently projected to occur around the end of 2007. We have received Fast Track designation from the U.S. Food & Drug Administration (FDA) for Favld. In addition to our Phase 3 clinical trial, Favld has been evaluated in several multi-center, open-label Phase 2 clinical trials involving more than 130 patients. Long-term follow-up data from our 89-patient Phase 2 clinical trial of Favld following Rituxan therapy in patients with follicular B-cell NHL suggest that the administration of Favld following Rituxan may extend TTP compared to historical data of Rituxan alone. We believe Favld may be effective in treating other types of B-cell NHL as well and have four additional Phase 2 clinical trials of Favld ongoing. We have also received an allowance from the FDA for an Investigational New Drug application for our second product candidate, FAV-201, for the treatment of cutaneous T-cell lymphoma.

## Commercialization— Preparing for launch

We are nearing completion of our facility expansion to support commercial-scale manufacturing of Favld. We expect that the expanded capacity of this 80,000-square foot facility will be sufficient to supply Favld for up to 4,000 patients per year. We anticipate that the commercial-scale manufacturing facility will be validated and ready by the fourth quarter of 2007.



# FAVRILLE

## Cancer treatment— We make it personal

We are a biopharmaceutical company focused on the development and commercialization of patient-specific immunotherapies for the treatment of cancer and other diseases of the immune system. We have developed a proprietary technology to manufacture active immunotherapy products that are designed to stimulate a patient's immune system to mount a specific and sustained response to disease. Our lead product candidate, Favld, is currently under investigation in a pivotal Phase 3 clinical trial in patients with follicular B-cell non-Hodgkin's lymphoma (NHL). The American Cancer Society cites NHL as the sixth leading cause of death among cancers in the U.S. and the National Cancer Institute estimates that approximately 332,000 patients suffer from this disease. Follicular B-cell NHL is the most common form of the indolent disease. We believe that our proprietary technology will enable us to manufacture Favld in a timely and cost-effective manner, allowing us to offer treatment options not currently available to physicians and patients.

## Our lead product—Favld®

Favld is an active immunotherapy that is based upon unique genetic information extracted from a patient's tumor. We are developing Favld for use following treatment with existing standards of care to extend time to disease progression (TTP) in patients with B-cell NHL. We currently have exclusive worldwide commercialization rights to Favld.





### *To Our Shareholders,*

This is an exciting and unprecedented time for Faville as we near the end of a long development path for our lead product candidate, Favld®. We find ourselves on the brink of pivotal Phase 3 clinical trial data for Favld just as other cancer immunotherapies are nearing key decision points, piquing momentum and excitement among patients, physicians and investors.

Favld is a patient-specific, active immunotherapy for B-cell non-Hodgkin's lymphoma (NHL) that is based upon unique genetic information extracted from a patient's tumor. We completed patient enrollment in our placebo-controlled, double-blind, pivotal Phase 3 clinical trial of Favld following treatment with Rituxan®, the current standard of care, in January 2006 with 349 patients randomized into the trial.

Analysis of our primary endpoint, time to disease progression (TTP), is based upon the number of patients whose disease progresses in the trial and is currently projected to occur around the end of 2007. We will closely monitor the rate of progression in the trial in the coming months and update this projection as necessary.

In the meantime, here is a review of some recent milestones that we believe help position Favld for success:

- In November 2006, we announced the results of an interim analysis of a secondary endpoint, response rate improvement, in our pivotal Phase 3 clinical trial of Favld. While our independent Data Monitoring Committee concluded that the interim analysis did not demonstrate a statistically significant difference between treatment and control groups for the secondary endpoint, we were encouraged by the high rate of complete remissions in the blinded data, which we believe indicates that we have enrolled an appropriate population for an assessment of our primary endpoint, TTP.
- We reported long-term follow-up data from our Phase 2 clinical trial of Favld following Rituxan therapy at the American Society of Hematology Annual Meeting in December 2006. The data showed that patients who had a clinical response to Rituxan and then received Favld had not reached median TTP 37 months from the end of patient enrollment. Furthermore, 12 of the 16 patients who attained a complete remission in the trial remained progression-free over the same period. We are especially encouraged about the durability of response in Favld-treated patients from this Phase 2 trial.
- In February 2007, we entered into an agreement with Berlex Inc., a U.S. affiliate of Bayer Schering Pharma AG. This agreement helps pave the way for commercialization, including reimbursement, of Favld in combination with Leukine® (sargramostim, GM-CSF), a growth factor designed to enhance a patient's immune response. We believe the use of these two products together is important in order to maximize the benefit to lymphoma patients.

I would like to take this opportunity to thank our employees, investors, clinical investigators, study coordinators and, most of all, the patients in our trials for their continued support. As we draw nearer to our Phase 3 analysis, we remain confident in the design, execution and outcome of our trial—an outcome that will define the future of our Company and, we believe, the future treatment of B-cell non-Hodgkin's lymphoma.

Sincerely,

**John P. Longenecker, Ph.D.**

President & Chief Executive Officer

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

FORM 10-K

RECD S.E.C.

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

For the fiscal year ended December 31, 2006

1086

Or

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

For the transition period from to

Commission File Number 000-51134

**Favrille, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

33-0892797  
(I.R.S. Employer  
Identification No.)

10445 Pacific Center Court  
San Diego, CA 92121  
(Address of principal executive offices, including zip code)

(858) 526-8000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:  
Common Stock, \$0.001 par value per share

Securities registered pursuant to Section 12(g) of the Act:  
None  
(Title of class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the last sale price of the common stock reported on the Nasdaq National Market on June 30, 2006 was \$72,239,394. For purposes of determining this amount, Registrant has defined affiliates to include (a) the executive officers and directors of the Registrant on June 30, 2006 (b) stockholders affiliated with our directors and (c) each stockholder that had informed Registrant by June 30, 2006 that it was the beneficial owner of 10% or more of the outstanding common stock of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 22, 2007, there were 32,503,721 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Location in Form 10-K

Incorporated Document

Part III: Items 10, 11, 12 13 and 14

Proxy Statement for 2007 Annual Meeting of Stockholders

**FAVRILLE, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006**

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## Cautionary Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements that involve many risks and uncertainties. These statements relate to future events and our future performance and are based on current expectations, estimates, forecasts and projections about the industry in which we operate and the beliefs and assumptions of our management. In some cases, you can identify forward-looking statements by terms such as "would," "could," "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "potential," "targets," "seek," or "continue," the negative of these terms or other variations of such terms. In addition, any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business and other characterizations of future events or circumstances, are forward-looking statements. These statements are only predictions based upon assumptions that are believed to be reasonable at the time, and are subject to risk and uncertainties. Therefore, actual events or results may differ materially and adversely from those expressed in any forward-looking statement. In evaluating these statements, you should specifically consider the risks described in Item 1A of Part I and elsewhere in this Form 10-K. These factors may cause our actual results to differ materially from any forward-looking statements. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

### PART I

#### Item 1. *Business*

##### Overview

We are a biopharmaceutical company focused on the development and commercialization of targeted immunotherapies for the treatment of cancer and other diseases of the immune system. We have developed a proprietary technology that enables us to manufacture active immunotherapy products that are designed to stimulate a patient's immune system to mount a specific and sustained response to disease. Our lead product candidate, FavId<sup>®</sup>, is an active immunotherapy for the treatment of B-cell non-Hodgkin's lymphoma, or NHL. We initiated a randomized, placebo-controlled, double-blind pivotal Phase 3 clinical trial of FavId in patients with follicular B-cell NHL in July 2004 and completed patient enrollment in January 2006 with 349 patients randomized into the trial. In January 2006 we announced that we received Fast Track designation from the U.S. Food and Drug Administration, or FDA, for FavId.

FavId is being developed for use following treatment with existing standards of care to extend time to disease progression, or TTP, in patients with B-cell NHL. Our Phase 3 clinical trial is designed to evaluate FavId's ability to extend TTP in patients with follicular B-cell NHL following treatment with Rituxan<sup>®</sup>, which is the current standard of care for indolent B-cell NHL. Follicular B-cell NHL is the most common form of the indolent disease. We presented the results of an interim analysis of a secondary endpoint, response rate improvement, in our Phase 3 clinical trial of FavId at the American Society of Hematology, or ASH, Annual Meeting in Orlando, Florida, in December 2006. While our independent Data Monitoring Committee concluded that the interim analysis did not demonstrate a statistically significant difference between treatment and control groups for the secondary endpoint, we were encouraged by the high rate of complete remissions in the blinded data, which we believe indicates that we have enrolled an appropriate population for an assessment of our primary endpoint, TTP. Analysis of TTP is event-driven and is currently projected to occur during the fourth quarter of 2007.

In addition to our pivotal Phase 3 clinical trial, FavId has been evaluated in several multi-center, open-label Phase 2 clinical trials involving more than 130 patients. Long-term follow-up data from our 89-patient Phase 2 clinical trial of FavId following Rituxan therapy in patients with follicular B-cell NHL suggest that the administration of FavId following Rituxan may extend TTP compared to historical data of Rituxan alone. In particular, the data showed that patients who had a clinical response to Rituxan and then received FavId had not reached median TTP 37 months from the end of patient enrollment. Furthermore, 11 of the 13 patients in the trial who converted to complete remission following the initiation of FavId remained in complete remission as of January 2007.

We believe that our proprietary technology will enable us to manufacture FavId in a timely and cost-effective manner and will therefore allow us to offer a treatment option not currently available to physicians and patients.

We believe FavId may be effective in treating other types of B-cell NHL. Four additional Phase 2 clinical trials of FavId are ongoing. One of these clinical trials is being conducted under a separate physician-sponsored Investigational New Drug, or IND, application in the United States. Moreover, we believe our active immunotherapy expertise and proprietary manufacturing technology may enable us to develop additional product candidates for other oncology indications, such as T-

cell lymphoma. In June 2006, we received an allowance from the FDA for an IND for our second product candidate, FAV-201, for the treatment of cutaneous T-cell lymphoma. We have retained exclusive worldwide commercialization rights to all of our product candidates.

We were incorporated in Delaware in January 2000.

## **The Immune System**

The immune system is the body's major defense against foreign pathogens, such as viruses and bacteria. The principal cells that make up the immune system are termed white blood cells. A subset of white blood cells known as lymphocytes is essential in generating an effective immune response to disease-causing agents. Lymphocytes consist primarily of B-cells and T-cells, which normally recognize and respond to antigens found within proteins derived from foreign pathogens. The B-cell receptor that recognizes an antigen is called an antibody. Once B-cells recognize antigens, they initiate a sequence of events that results in the immune system's production of large amounts of antibodies specific to that antigen. These antibodies then circulate throughout the body and bind to their target antigen, thereby flagging pathogens for destruction. This type of immune response is known as the antibody-based, or humoral, immune response.

T-cells are responsible for carrying out what is known as the cell-mediated immune response. T-cell receptors recognize antigens presented on the surface of other cells. When a T-cell recognizes its target, it responds in one of two ways. Either it destroys the target directly, or it produces a variety of proteins that cause the growth and activation of itself and other T-cells and B-cells, which can then destroy the target.

Although any one B-cell or T-cell can recognize and respond to only a single antigen, the human immune system has evolved such that the collective B-cell and T-cell populations can respond to virtually every possible foreign pathogen that a person may encounter in his or her lifetime. Furthermore, the humoral and cell-mediated immune responses have an additional feature of "memory," which enables B-cells and T-cells to recall an interaction with a foreign antigen and to respond to this antigen in a more rapid and aggressive fashion in the future.

The immune system is generally very effective in destroying pathogens—viruses, bacteria, or other foreign microorganisms that it recognizes as foreign. For this reason, a properly functioning immune system is highly regulated to ensure that its destructive power is not directed against normal tissue. If this regulation breaks down, an immune response may be generated against normal tissue, which can lead to autoimmune diseases, such as multiple sclerosis, rheumatoid arthritis and lupus. In the case of cancer, this strict regulation of the immune system may prevent an effective immune response from being mounted because of the body's inability to distinguish the cancer as foreign. Researchers believe that teaching the immune system to recognize the proteins associated with cancer cells as foreign will enable the immune system to identify and eliminate cancers, such as lymphoma.

## **Immunotherapy**

Immunotherapy is designed to use a person's immune system to fight diseases, including cancer. Immunotherapy enables the immune system to target and destroy diseased cells and has far fewer side effects than other therapies, such as surgery, chemotherapy and radiation therapy. There are two types of immunotherapy used to treat cancer: passive immunotherapy and active immunotherapy.

Passive immunotherapy utilizes large doses of infused antibodies that bind to antigens primarily expressed by a tumor cell and by few or no normal cells. These antibodies circulate throughout the bloodstream, binding to antigens on targeted cells, thereby flagging them for destruction. One of the most widely used passive immunotherapies for the treatment of B-cell NHL is Rituxan, either alone or in combination with chemotherapy. Despite their widespread use in fighting cancer, passive immunotherapies such as Rituxan suffer from significant limitations, including a limited duration of efficacy and the development of resistance. Additional passive immunotherapies have attempted to overcome the shortcomings of Rituxan by linking antibodies to radioactive molecules that can directly destroy the cell to which the antibody is bound. However, improvements in time to disease progression, if any, have been modest.

Active immunotherapy teaches the patient's own immune system to recognize and fight cancer. Active immunotherapy is designed to program the immune system to generate a sustained and robust humoral (B-cell) and cell-mediated (T-cell) immune response. Idiotypic immunotherapy, including our product candidate, FavId, for the treatment of B-cell NHL, is an example of active immunotherapy. In the case of B-cell NHL, the antibody protein made by a person's B-cell NHL is used as

a target for immune attack. The unique antigens in this antibody protein are referred to as the idiotype. The immune system can differentiate between lymphoma cells and normal B-cells based on their idiotype. As a result, following successful idiotype immunotherapy, a patient's immune response is specific to their B-cell lymphoma.

### **Development of Active Idiotype Immunotherapy**

Active idiotype immunotherapy has been studied in patients with B-cell NHL since the late 1980's and has shown substantial promise in clinical trials. Trials conducted at the Stanford University Medical Center and the NCI evaluated the use of active idiotype immunotherapy in treating patients with indolent B-cell NHL. The results suggest that active idiotype immunotherapy significantly increases the duration of response in patients previously placed into remission with chemotherapy. Remission is defined as at least a 50% reduction in tumor burden. The immunotherapy administered in both the Stanford and NCI trials was similar to FavId in that it involved the combination of an idiotype protein derived from a patient's tumor with a foreign protein, keyhole limpet hemocyanin, or KLH. KLH is a protein derived from shellfish that elicits a strong immune response.

In the Stanford trial, 21 of 41 patients treated with idiotype immunotherapy mounted an immune response to their idiotype protein. The median TTP in these patients was calculated to be 7.9 years, compared to a median TTP of 1.3 years for the patients who failed to mount an immune response. For purposes of this trial, TTP was defined as the interval between the date of last dose of chemotherapy and the recurrence of disease. The median TTP for the responding patients was calculated based on available data using a statistical method known as Kaplan-Meier analysis, which allows for the estimation of a median time when not all of the patients have reached the event being measured at the time of analysis. The results from this trial were published in the medical journal *Blood* in May 1997.

In an attempt to increase the idiotype-specific immune response, the NCI trial supplemented the idiotype immunotherapy with granulocyte macrophage colony stimulating factor, or GM-CSF, a white blood cell growth factor designed to enhance the immune response. Lymphoma-specific immune responses were reported for 19 of the 20 patients in the trial, and the most recent update from this trial in December 2005 indicates that with a median follow-up time of 9.2 years, 45% of patients remain in continuous complete remission with an overall survival rate of 90%. The trial also showed that the immunotherapy converted eight of 11 patients tested to a molecular remission, which means no evidence of tumor could be seen even at the more sensitive level of DNA detection. The preliminary results from the NCI trial were published in the medical journal *Nature Medicine* in October 1999, and the most recent update from this trial was published in the medical journal *Blood* in November 2003.

### **Barriers to Commercialization**

Although the Stanford and NCI clinical trials demonstrated favorable results, substantial manufacturing difficulties have limited further development of an active idiotype immunotherapeutic approach to the treatment of B-cell NHL. The manufacturing process used to produce the idiotype immunotherapies studied at Stanford and the NCI has lengthy and inconsistent production timelines and is labor-intensive, with a reported manufacturing failure rate as high as 15%. As a result, we believe this process would make active idiotype immunotherapies produced using this process difficult to commercialize.

### **Our Solution for the Commercial Production of Active Idiotype Immunotherapy**

We have developed a proprietary technology that we believe enables us to overcome historical limitations to the manufacturing and commercialization of active idiotype immunotherapies. Our technology utilizes an insect-cell virus that carries genetic information that is identical to a patient's lymphoma. By introducing this virus into an insect cell line, we can produce sufficient quantities of idiotype protein for our immunotherapy. We believe our manufacturing process has the following benefits:

- **Rapid Production Cycle.** Our unique and proprietary manufacturing process allows for the manufacture of FavId for delivery to patients in eight weeks. We believe our production cycle time is a number of months shorter than previously reported cycle times for manufacturing idiotype immunotherapies for B-cell NHL. Our production timeline allows us to administer FavId at what we believe is the optimal time following treatment with Rituxan.

- *Reliable Manufacturing.* Our underlying production method for each patient will not change regardless of the number of units of FavId produced. This small-scale unit operation is easily replicated to produce multiple patient therapies simultaneously without the risks associated with traditional scale-up for commercial production.

- *Automation.* This small-scale unit operation is amenable to automation. The time required to identify the genetic information used to construct the insect-cell expression vector has been reduced by technological advances, including automation, some of which are the result of the human genome project. We believe that many other steps in the production of FavId can be automated.

Our production process requires standardized small volumes, is readily reproducible, and requires limited production time. As a result, we believe our cost of production can allow for a commercially viable product with gross margins similar to those seen for other biopharmaceuticals and enable physicians to use FavId in concert with all existing standards of care for indolent B-cell NHL, including Rituxan.

### Our Development Programs

The chart below summarizes the status of ongoing, recently completed and currently planned clinical and preclinical development programs. We have retained exclusive worldwide commercialization rights to all of our product candidates.

<b>Product</b>	<b>Indication</b>	<b>Patient Population</b>	<b>Status</b>
<b>FavId</b>			
Following Rituxan	Follicular B-cell NHL	Treatment-naïve or relapsed/refractory patients(1)	Phase 3 trial enrollment complete: analysis of primary endpoint, TTP, anticipated in the fourth quarter of 2007
Following Rituxan	Follicular B-cell NHL	Treatment-naïve or relapsed/refractory patients	Phase 2 trial enrollment complete: patients in long-term follow-up
Single agent	Indolent B-cell NHL	Relapsed/refractory patients	Phase 2 trial enrollment complete: patients in long-term follow-up
Following autologous stem cell transplant	Indolent B-cell NHL	Patients eligible for autologous stem cell transplant	Phase 2 trial enrollment complete(2)
With maintenance Rituxan	Indolent B-cell NHL	Treatment-naïve patients	Phase 2 trial enrolling patients
Single agent	Non-follicular B-cell NHL	Treatment-naïve or relapsed/refractory patients	Phase 2 trial enrolling patients
Following prior therapy	Follicular B-cell NHL	Patients who progressed in our Phase 3 trial without receiving FavId	Phase 2 trial enrolling patients
<b>FAV-201</b>			
Single agent	T-cell lymphoma	Previously treated patients	Received allowance from FDA for IND
<b>Autoimmune Disease</b>	Not applicable	Not applicable	Preclinical development

(1) Patients are considered relapsed if their lymphoma has returned after a response to prior therapy. Patients are considered refractory if they have not responded to prior treatments.

(2) This trial is physician-sponsored, which means that a physician, rather than Faville, is responsible for managing the conduct of the trial and the resulting data. We provided FavId at our own expense for use in this physician-sponsored trial.

## ***FavId for B-Cell NHL***

### ***Overview***

Our lead product candidate, FavId, is an active immunotherapy that is based upon unique genetic information extracted from a patient's tumor. We initiated a pivotal Phase 3 clinical trial evaluating FavId in treatment-naïve or relapsed or refractory follicular B-cell NHL patients following treatment with Rituxan in July 2004 and completed patient enrollment in January 2006. Follicular lymphoma accounts for the majority of all indolent B-cell NHL cases. In addition to our pivotal Phase 3 clinical trial, FavId has been evaluated in several multi-center, open-label Phase 2 clinical trials of FavId involving more than 130 indolent B-cell NHL patients. We also have Phase 2 clinical trials of FavId ongoing in other B-cell NHL indications. One of these clinical trials is being conducted under a separate physician-sponsored IND in the United States. We currently retain exclusive worldwide commercialization rights to FavId.

### ***Market Opportunity***

The American Cancer Society cites NHL as the sixth most common form of cancer and the sixth leading cause of death among cancers in the United States. The American Cancer Society predicts that there will be about 63,190 new cases of NHL in the U.S. in 2007, and the NCI has estimated that approximately 332,000 patients suffer from this disease. B-cell NHL is a cancer of B-cell lymphocytes, the body's white blood cells principally responsible for fighting disease. Approximately 85% of NHL patients in the United States have B-cell NHL. We believe that approximately half of these patients have the indolent form of the disease. Although indolent B-cell NHL is slow-growing, it is incurable with existing therapies and inevitably fatal. The median survival time for patients diagnosed with advanced stages of indolent B-cell NHL is estimated to be between seven and ten years.

### ***Current Treatments***

**Overview.** B-cell NHL is composed of a diverse group of malignancies with varying patterns of behavior and responses to treatment. Both the prognosis for patients with this disease, and the treatment that they are likely to receive, depend on the histologic type and stage. B-cell NHL is commonly divided into two groups: indolent NHL and aggressive NHL. Indolent B-cell NHL has a relatively good prognosis, with a median survival as long as 10 years. Early-stage indolent B-cell NHL can be effectively treated and often cured with radiation therapy alone. Patients with advanced stage indolent B-cell NHL are not considered curable but generally respond to treatment with a remission. These remissions are generally temporary, however, and patients require additional treatments when they relapse. Aggressive B-cell NHL has a shorter natural history. Only 50% of these patients can be cured with chemotherapy alone or with combinations of chemotherapy and Rituxan. If patients relapse after treatment, the vast majority of relapses occur in the first two years following therapy.

**Chemotherapy.** Prior to Rituxan's availability, chemotherapy was traditionally used as the primary therapy for most patients with B-cell NHL. Chemotherapy is typically administered in repeated cycles over three to eight months and can substantially reduce the amount of lymphoma and often achieve remission. Patients receiving chemotherapy generally experience a number of side effects, including fatigue, nausea, hair loss and increased risk of infection. These side effects may result in the need for supportive care, including additional therapies and hospitalization. Patients also experience late side effects such as sterility, myelodysplastic syndromes, second cancers, and heart dysfunction. The toxicity and inconvenience of chemotherapy can impose a heavy strain on a patient's overall quality of life.

**Passive Immunotherapy.** Several passive immunotherapy products have been approved for the treatment of B-cell NHL, including Rituxan, Zevalin and Bexxar. Rituxan, a monoclonal antibody, is the leading passive immunotherapy approved for the treatment of B-cell NHL and is being used for both indolent and aggressive B-cell NHL. Standard treatment with Rituxan alone involves four weekly intravenous infusions over a 22-day period. Rituxan is considered to be significantly less toxic to the bone marrow than chemotherapy. Unfortunately, as with patients with indolent B-cell NHL who receive chemotherapy, patients treated with Rituxan eventually relapse. Several clinical trials have suggested that additional doses of Rituxan as a maintenance therapy can improve the time before patients with follicular B-cell NHL relapse. In addition, combinations of Rituxan and chemotherapeutic or immunostimulatory drugs at various doses and schedules may provide patients with an increase in TTP over that expected with Rituxan alone. Rituxan can induce remission in approximately 50% of patients with indolent B-cell NHL and, when used in combination with chemotherapy, in approximately 80% of patients with follicular B-cell NHL. In these responding patients, the remission lasts approximately one to three years. When administered with chemotherapy to patients with aggressive B-cell NHL, Rituxan can increase the cure rate and the TTP.

Rituxan used either alone or in combination with another therapy is the current standard of care for the treatment of B-cell NHL patients. Rituxan is also approved for treatment of rheumatoid arthritis. Sales of Rituxan for all indications have grown from \$162 million in 1998 to approximately \$2.1 billion in 2006. Our clinical registration strategy involves the administration of FavId to the group of patients who would receive Rituxan, that is combine active and passive immunotherapies. Since Rituxan is the current standard of care, we believe this approach of FavId used in combination with Rituxan treatment will allow the largest number of patients with B-cell NHL to benefit.

### *Clinical Development*

***Pivotal Phase 3 Clinical Trial – FavId Following Rituxan.*** We initiated a Phase 3 clinical trial of FavId following Rituxan induction therapy in patients with follicular B-cell NHL in July 2004 and completed enrollment in January 2006 with 349 patients randomized into the trial. The randomized, double-blind, placebo-controlled trial is being conducted at 67 oncology centers and more than 100 sites across the U.S. Approximately 80 percent of the patients enrolled are treatment-naïve, with the remainder either relapsed from or refractory to prior therapies. The primary endpoint of the trial is TTP, which in this protocol is defined as the time that elapses between randomization and disease progression.

We obtain tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId. In addition, a CT scan is conducted in order to measure tumor burden before Rituxan treatment. Each patient then receives the standard four doses of Rituxan alone at one-week intervals while the patient's FavId is being manufactured. Five weeks after the last dose of Rituxan is administered, the patient is re-evaluated and a CT scan is conducted to assess the patient's response to Rituxan. A patient whose disease remains stable or improves following treatment with Rituxan is randomized to receive either FavId with GM-CSF or placebo with GM-CSF. During the induction phase, randomized patients receive monthly injections of FavId or placebo for six months. If a patient's lymphoma remains under control after the induction phase, the patient receives maintenance injections of FavId or placebo given every other month for a year and then every third month until the time of disease progression. Throughout the trial, patients receive CT scans every three months to determine whether their lymphoma is under control. During the trial, patients do not receive any cancer therapy other than that administered in the trial. However, once a patient's disease progresses, the patient's participation in the trial terminates.

We presented the results of an interim analysis of a secondary endpoint, response rate improvement, in our Phase 3 clinical trial of FavId at the American Society of Hematology, or ASH, Annual Meeting in Orlando in December 2006. While our independent Data Monitoring Committee concluded that the interim analysis did not demonstrate a statistically significant difference between treatment and control groups for the secondary endpoint, we were encouraged by the high rate of complete remissions in the blinded data, which we believe indicates that we have enrolled an appropriate population for an assessment of our primary endpoint, TTP. Analysis of TTP is event driven and is currently projected to occur during the fourth quarter of 2007.

We have a Special Protocol Assessment, or SPA, from the FDA for our Phase 3 clinical trial. In the SPA process, the FDA reviewed the design, size and planned analysis of our Phase 3 clinical trial and provided comments regarding the trial's adequacy to form a basis for approval of a Biologics Licensing Application, or BLA, if the trial is successful in meeting its predetermined objectives. The FDA's written agreement is binding, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety or effectiveness of a product candidate is identified after the Phase 3 clinical trial is commenced.

In January 2006 we announced that we received Fast Track designation from the FDA for FavId. Fast Track designation is granted for a new drug that is intended to treat a serious or life-threatening condition and demonstrates the potential to address an unmet medical need and as a result is eligible for priority review by the FDA. This action by the FDA has the potential to save Faville valuable time in the regulatory approval process and serves as an acknowledgement of the potential for FavId in the treatment of follicular B-cell NHL.

***Phase 2 Clinical Trial – FavId Following Rituxan.*** We initiated a Phase 2 clinical trial of FavId in patients with follicular B-cell NHL who were candidates for Rituxan therapy in June 2002. Initially, this trial was limited to relapsed or refractory patients who had previously undergone treatment with Rituxan, chemotherapy or both. In April 2003, we expanded the entry criteria for this trial to include patients with no prior treatment for their lymphoma. The open-label Phase 2 trial was conducted at 20 sites. Enrollment in this trial was completed in December 2003. A total of 103 patients were enrolled in the trial, of which 89 had stable disease or a better response to Rituxan and received FavId, including 54 who were relapsed from or refractory to prior treatments and 35 who were treatment-naïve.

We obtained tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId. In addition, a CT scan was conducted in order to measure tumor burden before Rituxan treatment. Each patient then received four doses of Rituxan alone at one-week intervals while the patient's FavId was being manufactured. Approximately eight weeks after the last dose of Rituxan, the patient was re-evaluated and a CT scan was conducted to assess the patient's response to Rituxan. Patients whose disease remained stable or improved following Rituxan treatment received monthly injections of FavId and GM-CSF for six months. If a patient remains progression free after this induction period, the patient continues to receive maintenance injections of FavId given every other month for a year and then every third month until the time of disease progression. Throughout the trial, patients receive CT scans every three months to determine whether their lymphoma is under control. During the trial, patients do not receive any cancer therapy other than that administered in the trial. However, once a patient's disease progresses, the patient's participation in the trial terminates.

Long-term follow-up data from this Phase 2 trial were reported at the ASH Annual Meeting in Atlanta, Georgia, in December 2006. In an oral presentation, co-primary investigator Jane N. Winter, M.D., Feinberg School of Medicine at Northwestern University, reported that the administration of FavId following Rituxan induction therapy appears to extend TTP compared to historical data in patients with follicular B-cell NHL. In particular, the data showed that patients who had a clinical response to Rituxan and then received FavId had not reached median TTP 37 months from the end of patient enrollment. Furthermore, 11 of the 13 patients in the trial who converted to complete remission following the initiation of FavId remained in complete remission as of January 2007.

The overall clinical response rate in the Phase 2 trial increased from 47% at month 3 following Rituxan alone to 63% following the initiation of FavId.

The positive interim results found in this Phase 2 clinical trial do not guarantee final results, and our positive assessment of FavId in this clinical trial could differ from our assessment of FavId following completion of this trial or the pending Phase 3 clinical trial. We believe an analysis of the characteristics of those patients in our trial whose disease relapsed compared to those whose disease had not allowed us to optimize the design of our pivotal Phase 3 clinical trial.

**Phase 2 Clinical Trial – FavId as a Single Therapeutic Agent in Relapsed or Refractory NHL Patients.** In September 2002, we completed enrollment of a Phase 2 clinical trial evaluating FavId as a single therapeutic agent in indolent B-cell NHL patients who were either relapsed from, or refractory to, prior treatments. The trial was conducted at multiple sites and was designed to determine whether use of FavId alone could stimulate an immune response and whether this response would result in a clinical benefit. We obtained tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId. In addition, a CT scan was conducted in order to measure tumor burden before FavId treatment. Each patient received monthly injections of FavId and GM-CSF for six months. If a patient's lymphoma remains under control after the induction period, the patient receives maintenance injections of FavId given every other month for a year and then every third month until TTP.

Throughout the trial, patients receive CT scans every three months to determine whether their lymphoma is under control. During the trial, patients do not receive any cancer therapy other than that administered in the trial. However, once a patient's disease progresses, the patient's participation in the trial terminates.

Results from the single agent trial, published in the July 2006 issue of the *Journal of Clinical Oncology*, showed that FavId as a single agent is active and well tolerated in previously treated and relapsed patients with indolent B-cell NHL. The most common adverse events reported were mild to moderate injection site reactions. The median TTP for the 31 evaluable patients was 13.5 months. In January 2007, one patient remained progression free for 56 months.

These results are encouraging compared to results from similar patients treated with other lymphoma biologic therapies. In a clinical trial conducted by Witzig and reported in the May 2002 issue of the *Journal of Clinical Oncology*, patients with follicular NHL treated with Rituxan alone had a median TTP of 10.2 months and a median duration of response of 12.1 months. In addition, patients with follicular NHL treated with Zevalin had a median TTP of 12.6 months with a median duration of response of 18.5 months. Similarly, in a trial conducted by McLaughlin and reported in the August 1998 issue of the *Journal of Clinical Oncology*, patients treated with Rituxan alone had a TTP of 9.0 months. Median duration of response in that trial was 11.2 months.

	<u>Single Agent FavId</u>	<u>Witzig Rituxan</u>	<u>McLaughlin Rituxan</u>	<u>Witzig Zevalin</u>
Patients.....	31	58	166	55
TTP (months).....	13.5	10.2	9.0	12.6

This clinical trial demonstrated that FavId as a single agent is well tolerated and has activity in pretreated patients with relapsed indolent B-cell NHL. Patients with two or fewer prior therapies and with tumor burdens of less than 50 square centimeters at initiation of the trial appeared more likely to respond to administration of FavId than more heavily pretreated patients or patients with larger tumors.

**Phase 2 Clinical Trial – FavId Following Autologous Stem Cell Transplantation.** Patient enrollment for a physician-sponsored Phase 2 clinical trial evaluating FavId following high-dose chemotherapy and autologous stem cell transplantation in patients with NHL began in November 2000. Autologous stem cell transplantation involves removing vital blood cells from a patient before administering large doses of chemotherapy. After chemotherapy, the blood cells are returned to the patient to speed recovery from the chemotherapy treatment. This trial, now closed to patient enrollment, is currently being conducted at two sites.

This trial is designed to evaluate the ability of FavId to induce humoral and cell-mediated immune responses, and to induce or maintain complete clinical or molecular remission, following autologous stem cell transplantation. In addition, the trial is evaluating the correlation of specific T-cell populations with immune responsiveness to FavId, as well as the safety of FavId following autologous stem cell transplantation. After we obtain tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId, patients undergo autologous stem cell transplantation using standard regimens. At three months following transplantation, patients receive the first of five monthly injections of FavId. Patients are assessed at fixed intervals for safety, development of immune responses to their tumor idiotype, and for evidence of molecular remissions.

Interim data from this trial were presented at the annual meetings of the American Society for Blood and Marrow Transplantation (ASBMT) and the Center for International Blood and Marrow Transplant Research (CIBMTR) in Keystone, Colo., in February 2007. A total of 15 patients were treated in the trial, of which nine remained in complete remission up to 61 months post-transplant. The median number of prior regimens for all patients was three, ranging from one to 10. The data showed that the majority of patients in the trial developed a rapid and tumor-specific immune response, often measured following a single dose of FavId.

**Phase 2 Clinical Trial – FavId Combined with a Maintenance Rituxan Schedule.** Patient enrollment for a multi-center, physician-sponsored Phase 2 clinical trial evaluating FavId in combination with maintenance Rituxan for the treatment of indolent B-cell NHL began in May 2004. We assumed sponsorship of the IND in August 2004. The trial is open to treatment-naïve patients with indolent B-cell NHL and is designed to enroll a total of 56 patients.

This trial is intended to demonstrate an improvement over the results of certain prior trials using maintenance Rituxan for the treatment of indolent B-cell NHL. In these prior trials patients received four weekly doses of Rituxan every six months for two years. The trials demonstrated a median TTP of 34 months for patients with indolent B-cell NHL treated with maintenance Rituxan. Despite this long TTP, patients still experienced a high relapse rate and do not appear to be cured of their disease. We believe that by incorporating FavId into a schedule of maintenance Rituxan, patients may experience an increased TTP beyond what would be expected from maintenance Rituxan alone.

This trial is designed to evaluate the safety of this regimen, and to assess its efficacy, based on the endpoints of response rate and event-free survival. Event-free survival is defined as the time period from the start of Rituxan to the time of disease progression or death. We obtain tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId. In addition, a CT scan is conducted in order to measure tumor burden before the start of Rituxan treatment. Patients receive the same dose and schedule of maintenance Rituxan as was administered in the prior trials of maintenance Rituxan. FavId is incorporated into this treatment regimen starting on the third month and is administered monthly for the first 12 months, every other month for the second 12 months, and every three months thereafter. FavId is not administered during those months when patients receive Rituxan. With each FavId administration, GM-CSF is administered on four consecutive days beginning on the day of such FavId administration. Throughout the trial, patients receive CT scans every three months to determine whether their lymphoma is under control. During the trial, patients do not receive any cancer therapy other than that administered in the trial. However, once a patient's disease progresses, the

patient's participation in the trial terminates.

**Phase 2 Clinical Trial – FavId in Non-follicular B-cell NHL.** Patient enrollment for a Phase 2 clinical trial evaluating FavId in patients with non-follicular B-cell NHL was initiated in Europe in June 2005. The trial is open to patients with various non-follicular lymphomas who are either treatment-naïve for their lymphoma, relapsed or refractory following prior chemotherapy for their lymphoma, or relapsed following a prior response to Rituxan. The trial is expected to enroll 15 patients, but enrollment may be expanded if activity is seen in any specific patient subset.

This trial is designed to evaluate the efficacy of FavId in patients with non-follicular indolent NHL, based on overall response rate, duration of response, time to progression and event-free survival. We will obtain tumor cells via biopsy from each patient to establish the genetic profile of the tumor for our use in manufacturing the patient's FavId. In addition, a CT scan will be conducted in order to measure tumor burden before FavId treatment. FavId will be administered monthly for the first six months, every other month for the next 12 months, and every three months thereafter until disease progression. With each FavId administration, GM-CSF will be administered on four consecutive days beginning on the day of such FavId administration. Patients in the trial who need immediate therapy may receive Rituxan prior to administration of FavId and GM-CSF, while patients with more indolent disease that is not in need of immediate treatment may receive FavId and GM-CSF administered as a single agent. Throughout the trial, patients will receive CT scans every three months to determine whether their lymphoma is under control. During the trial, patients will not receive any cancer therapy other than that administered in the trial. However, once a patient's disease progresses, the patient's participation in the trial will terminate.

**Phase 2 Clinical Trial – FavId Following Prior Therapy.** We continue to enroll patients in our Phase 2 clinical trial of FavId in patients who have received prior therapy for their follicular B-cell NHL. This trial was designed primarily to provide FavId to those patients in our pivotal Phase 3 clinical trial who did not receive FavId. This would include patients who progressed after receiving Rituxan, and those patients who were randomized to placebo and later progressed. This trial is being conducted at sites participating in our Phase 3 clinical trial.

Prior to receiving FavId, these patients will be evaluated by their treating physician. If the physician feels that the patient is a candidate for receiving FavId alone, then we will provide the FavId previously manufactured for them in the pivotal trial for use as a single agent. In those patients who may require a more immediate reduction in the amount of their lymphoma, the treating physician will have the option of administering salvage treatment such as chemotherapy prior to the administration of FavId. We expect that many of these patients will be candidates for retreatment with Rituxan prior to starting FavId. In these patients we will be able to compare the TTP which occurs following their receipt of Rituxan on the pivotal trial with their TTP following the receipt of both Rituxan and FavId on this Phase 2 trial. We believe that this comparison will provide further insight into any contribution by FavId to extending TTP following treatment with Rituxan.

**Safety.** In November 2006, our independent Data Monitoring Board met and reviewed safety data from our pivotal Phase 3 clinical trial of FavId and recommended that we continue the trial as planned.

#### ***FAV-201 for T-cell Lymphoma***

Our product candidate FAV-201 is a patient-specific T-cell receptor-based immunotherapy. In June 2006, we received an allowance from the FDA for an IND for FAV-201. We intend to initiate a Phase 1/2 clinical trial evaluating the safety and biologic activity of FAV-201 in patients with cutaneous T-cell lymphoma. The trial will build upon preclinical data that suggest activity of an immunotherapy based on a T-cell receptor. Patients will be observed for evidence of specific cell-mediated and humoral immune responses to FAV-201, and any clinical responses will also be documented. The multi-center trial is expected to enroll approximately 30 patients.

#### ***Autoimmune Disease Candidate***

Autoimmune disease occurs when the body's immune system mistakenly attacks and destroys body tissue that it believes to be foreign. In certain instances, autoimmune disease can result from an outgrowth of a limited number of disease-causing lymphocytes that recognize self antigens. Preclinical studies have shown that immunotherapies may prevent or treat autoimmune diseases. We have initiated preclinical studies to evaluate whether immunotherapies manufactured in a fashion similar to FAV-201 will be effective in preventing or treating autoimmune disease, with an initial focus on multiple sclerosis.

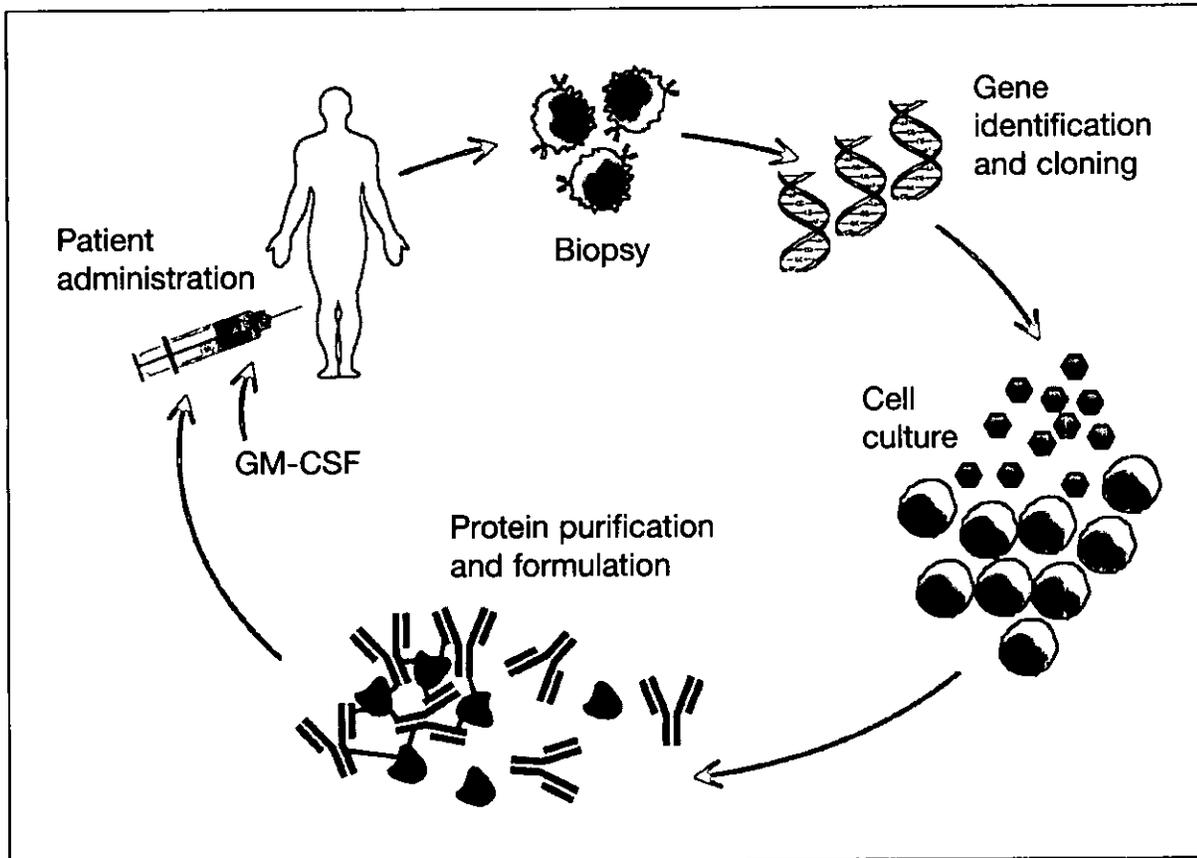
## Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of targeted immunotherapies for the treatment of cancer and other diseases of the immune system. Key elements of our strategy for achieving this goal are to:

- *Complete Clinical Development and Obtain Regulatory Approval for FavId.* We have completed enrollment in a pivotal Phase 3 clinical trial evaluating FavId for the treatment of follicular B-cell NHL. The trial is under an SPA from the FDA. We also received Fast Track designation for FavId from the FDA, which may result in an expedited review by the FDA. Analysis of the primary endpoint, TTP, is event-driven and is currently projected to occur during the fourth quarter of 2007.
- *Utilize Our Proprietary Technology to Develop Additional Product Candidates.* We believe that active immunotherapy may have applications in a number of additional diseases beyond B-cell NHL, such as T-cell lymphoma and autoimmune diseases, including multiple sclerosis. For example, we are currently studying a second product candidate, FAV-201, for the treatment of T-cell lymphoma and received an allowance from the FDA for an IND for FAV-201 in June 2006. In addition, we have initiated a preclinical development program to identify active immunotherapies for the treatment of multiple sclerosis.
- *Retain Commercialization Rights to Our Oncology Products.* We intend to focus our internal development efforts on FavId and other oncology product candidates. We hold exclusive worldwide commercialization rights to FavId without any obligation to pay royalties to any third party on sales. We currently plan to retain United States commercialization rights to these product candidates at least until we analyze data from the Phase 3 clinical trials (although we may consider partnering FavId sooner if we determine that circumstances warrant doing so). At that point, we expect to assess whether to market and sell FavId and future products in the United States directly through an internal sales force or together with a co-promotion partner. We intend to seek a commercialization and development partner outside of the United States. We intend to seek one or more collaborators to develop and commercialize our product candidates and programs for chronic autoimmune diseases, such as multiple sclerosis, in exchange for license fees, milestone payments and royalties.
- *Expand our Product Portfolio Through In-Licensing and Acquisitions.* We intend to capitalize upon our expertise in immunology, oncology, immunotherapy, clinical development and regulatory affairs to in-license or acquire complementary product candidates in various stages of development.

## Manufacturing and Supply

### *Our Proprietary Manufacturing Process*



Our process begins upon receipt of a patient's lymphoma biopsy, which the treating physician sends to our manufacturing facility. The process can be divided into the three phases described below.

#### *Gene Identification and Cloning*

First, we perform a genetic profile of a sample of the patient's tumor to identify and isolate the unique antibody genes that correspond to the patient's tumor idio type. We then insert these antibody genes into our proprietary insect cell-specific expression vectors. Our insect-cell expression vectors are DNA fragments that have all the genetic instructions needed for directing the production of full-length, recombinant, monoclonal antibodies.

#### *Cell Culture*

The next step in the process involves the use of an insect cell-specific expression vector to produce the recombinant idio type that forms the basis for FavId. We insert the expression vector into a continually growing insect cell line, which converts this genetic information into an insect cell virus, referred to as a baculovirus. We then add the baculovirus culture to a second insect cell line that subsequently secretes high levels of idio type protein. Within a few days, milligram quantities of this idio type protein are harvested. The cell culture medium used to grow the insect cells is completely devoid of any animal products, which we believe enhances the safety of the final product.

#### *Protein Purification and Formulation*

Finally, we perform a multi-step process to purify the idio type protein. Each step in this purification process results in idio type protein that is progressively more purified. In order to enhance the immune response, purified idio type protein is chemically linked to KLH. When the idio type and KLH complex is injected subcutaneously, the patient's immune system

reacts to both the foreign KLH and the patient's unique idiotype protein. We believe that, once activated, the patient's immune system will be able to recognize the idiotype protein on the cancer cell and more effectively fight the tumor.

### ***Manufacturing Facility***

We currently manufacture FavId for our clinical trials in our state-of-the-art, multi-product cGMP manufacturing facility which consists of approximately 26,000 square feet of space in an 80,000 square-foot leased facility. In September 2004, we received a manufacturing license from the California Department of Health Sciences. In November 2005, we signed an amended lease agreement to expand capacity within our existing manufacturing facility to support commercial-scale manufacturing of FavId<sup>®</sup>. This 80,000-square foot facility will be devoted to manufacturing and research and development, and is intended to give us the capacity to produce FavId to meet commercial needs while continuing to support additional clinical trials. We anticipate that the expanded capacity of our manufacturing facility will be sufficient to supply FavId for up to 4,000 patients per year. In September 2006, we leased an adjacent 48,000-square foot facility to house our corporate headquarters and warehousing operations. We anticipate that the commercial-scale manufacturing facility will be validated and ready for an FDA pre-approval inspection by the fourth quarter of 2007.

### ***Key Suppliers***

We currently depend on single source suppliers for critical raw materials used in the manufacture of FavId. We purchase KLH from biosyn Arzneimittel GmbH, or biosyn, which is currently the only supplier of KLH that has submitted a filing, known as a drug master file, with the FDA. In November 2004, we entered into an eight-year supply and license agreement with biosyn under which biosyn has agreed to supply us with KLH. We have purchased the required initial minimum supply of KLH and we have committed to minimum annual KLH purchase requirements during commercialization of FavId. In October 2006, we made a payment of \$50,000 to biosyn for the achievement of a milestone. An additional aggregate of up to \$250,000 will be due upon the achievement of certain milestones, the timing of which is not known at this time. Either party may terminate the supply agreement upon a breach by the other party that is not cured within 60 days or other events relating to insolvency or bankruptcy. There may be no other supplier of KLH of suitable quality for our purposes. In addition, we depend on a single source supplier for the cell growth media we use to produce FavId. We purchase this material from Expression Systems LLC, which in turn obtains several of the components used in the cell growth media from sole suppliers. Expression Systems LLC has submitted a drug master file with the FDA. We currently rely on purchase orders to obtain this material and do not have a supply agreement with Expression Systems. We intend to qualify a second source for the cell growth media or manufacture the cell growth media in house from commercially available raw materials but may not be able to do so. The GM-CSF that we administer with FavId is commercially available only from Berlex Laboratories, Inc. In February 2007, we entered into a clinical supply and study agreement with Berlex for clinical trials performed in the United States. The agreement provides for cooperation between Berlex and Faville on future clinical development and regulatory strategy relating to use of the two products in combination. GM-CSF is an FDA-approved and commercially available drug that may be purchased by physicians. Our current strategy for initial commercialization of FavId involves the administration of FavId following treatment with Rituxan. Rituxan is a passive immunotherapy for patients with NHL, which is also FDA-approved and is commercially available solely from Genentech and Biogen Idec. We currently rely on physicians to order and administer Rituxan to patients prior to the administration of FavId in our registration trial.

### ***Sales and Marketing***

We intend to market and sell FavId and future products in the United States either directly through an internal sales force or together with a co-promotion partner. Because the community and institutional referral networks of cancer treatment physicians in the United States are relatively small and well-established, we believe that a small, focused sales and marketing organization will enable us to effectively penetrate our target markets. Outside of the United States, we plan to establish strategic collaborations for the distribution and marketing of FavId.

We may enter into collaboration agreements with third parties with respect to other product candidates we develop, which may include co-marketing or co-promotion arrangements. Alternatively, we may grant exclusive marketing rights to one or more strategic collaborators in exchange for upfront fees, future milestone payments and royalties on sales.

We are currently in the process of acquiring the resources and experience necessary to market FavId or our other product candidates ourselves. We currently have no arrangements for distribution of our product candidates. Our future commercial success will depend on our ability to establish our own sales and marketing infrastructure or to collaborate with third parties that have greater sales and marketing experience and resources than our own.

## Competition

The development and commercialization of new pharmaceutical products for the treatment of cancer and autoimmune diseases is quite competitive, and we expect to face competition from numerous sources, including major pharmaceutical biotechnology companies, as well as specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have substantially greater financial and technical resources and development, production and marketing capabilities than we do. In addition, many of these companies have more experience than we do in preclinical testing, human clinical trials and manufacturing of biologic therapeutics, as well as in obtaining FDA and foreign regulatory approvals. We will also compete with academic institutions, governmental agencies and private organizations that are conducting research in the fields of cancer and autoimmune disease. Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense.

We are aware of a number of companies that are developing active immunotherapies to treat B-cell NHL. Genitope Corporation is evaluating idiotype immunotherapies in clinical trials. Genitope is conducting a Phase 3 clinical trial of its active idiotype immunotherapy product candidate in patients with follicular B-cell NHL who are in first remission following prior treatment with chemotherapy. Antigenics, Inc. completed a Phase 2 clinical trial evaluating its active immunotherapy candidate in indolent B-cell NHL patients. The NCI is also conducting a Phase 3 clinical trial of an active idiotype immunotherapy in collaboration with Biovest Inc., a subsidiary of Accentia Biopharmaceuticals.

Several companies are engaged in the development and commercialization of passive immunotherapy products for the treatment of B-cell NHL that may compete with FavId. Genentech and Biogen Idec are co-marketing Rituxan for the treatment of relapsed or refractory, indolent B-cell NHL. Biogen Idec is marketing Zevalin, its passive radioimmunotherapy product. GlaxoSmithKline plc is marketing Bexxar, its passive radioimmunotherapy product.

The most recent advances in the treatment of B-cell NHL have involved the combination of existing products and changes to approved schedules and doses, particularly for Rituxan. Numerous clinical trials reported in recent years have indicated that additional doses of Rituxan and maintenance dosing of Rituxan can improve the time to progression in patients who respond to therapy. Combination therapies involving chemotherapeutic or immuno-stimulatory drugs in combination with Rituxan at various doses and schedules may provide patients with an increase in time to progression over that expected with Rituxan alone. Accordingly, we may face competition as a result of developments in this area. New products are also in late stage development in B-Cell NHL that could pose a competitive threat for FavId. Products of note are humanized versions of Rituxan in development by Genentech and GlaxoSmithKline/Genmab, galiximab (anti-CD40) by Biogen Idec, Enzastaurin by Eli Lilly and Velcade by Millenium.

## Patents and Proprietary Rights

Our success will depend in large part on our ability to obtain and maintain patent protection for our products and technologies, preserve trade secrets and operate without infringing the intellectual property rights of others. We intend to prosecute and defend our intellectual property rights aggressively. Our policy is to seek patent protection for the inventions that we consider important to the development of our business. Currently we own U.S. Patent No. 6,911,204 together with four pending United States patent applications covering methods of treating immune system diseases, including B-cell and T-cell lymphomas, using our proprietary immunotherapy production methods, as well as methods for combining the idiotype immunotherapies with other therapies that are used to treat diseases of the immune system. We also have six issued patents and over twenty patent applications pending outside of the United States. Our intellectual property related to T-cell receptor-based immunotherapies includes an exclusive royalty-free license from the Sidney Kimmel Cancer Center to intellectual property developed by Dr. Daniel Gold while he was employed there prior to joining us. We have responsibility for the filing, prosecution and maintenance of patent rights associated with this license, but the intellectual property is jointly owned with the Sidney Kimmel Cancer Center which holds a license to use the technology for non-commercial research and educational purposes.

Although we believe these patent applications, if they issue as patents, will provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect our technology. In addition, any patents or patent rights we obtain may be circumvented, challenged or invalidated by our competitors.

While our product candidates are in clinical trials, and prior to commercialization, we believe our current activities in the United States fall within the scope of the exemptions against patent infringement provided by 35 U.S.C. Section 271(e) which covers activities related to developing information for submission to the FDA. As our product candidates progress toward commercialization, the possibility of an infringement claim against us increases. While we attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties' patents and proprietary rights, competitors or other parties may assert that we infringe on their patents or proprietary rights. Competitors or third parties may be issued patents that may cover subject matter that we use in developing, producing, or administering our products. In particular, we are aware of the following third party patents:

- Genentech and City of Hope National Medical Center hold patent rights relating to the expression of recombinant antibodies;
- Genitope holds patent rights relating to immunotherapy using idiotype proteins produced using T lymphoid cells for the treatment of B-cell lymphoma; and
- Schering Corp. holds patent rights relating to the use of GM-CSF as a vaccine adjuvant for use against infectious diseases.

Additionally, because patent prosecution can proceed in secret prior to issuance of a patent, third parties may obtain other patents with claims of unknown scope prior to the issuance of patents relating to our product candidates which they could attempt to assert against us. Further, as we develop our products, we may infringe the current patents of third parties or patents that may issue in the future.

We believe that we have valid defenses to any assertion that our product candidates, or the methods that we employ to manufacture them, infringe the claims of the patent held jointly by Genentech and City of Hope National Medical Center relating to the expression of recombinant antibodies. We also believe that the patent may be invalid and/or unenforceable. The relevant patent was issued to Genentech in 2001 in connection with the settlement of a district court action and an interference proceeding in the United States Patent and Trademark Office between Genentech and Celltech R&D Ltd. We believe other biotechnology companies are aware of and are considering the possible impact of this patent and that other companies have negotiated license agreements for this patent. We note that in May 2005, a third party filed a request for reexamination of this patent with the U.S. Patent and Trademark Office, requesting that the claims of this patent be reexamined as to their patentability. During reexamination the issued claims were rejected; proceedings before the U.S. Patent and Trademark Office continue. We have not attempted to obtain a license to this patent because we believe that properly construed claims do not cover activities related to the manufacture of FavId and FAV-201. If we decide to attempt to obtain a license for this patent, we cannot guarantee that we would be able to obtain such a license on commercially reasonable terms, or at all.

We also believe that we have valid defenses to any assertion that our product candidates infringe the claims of the patent held by Genitope relating to immunotherapy using idiotype proteins produced using T-lymphoid cells for treatment of B-cell lymphoma, and the claims of the patent held by Schering Corp. relating to use of GM-CSF as a vaccine adjuvant for use against infectious diseases. The relevant Genitope patent issued in 1999. We believe that FavId and FAV-201 and the methods we use to manufacture them do not infringe the claims of the patent. The relevant Schering patent issued in 1997. We believe that FavId and FAV-201 and the methods we use to manufacture them do not infringe the claims of the patent and that the claims of the patent are invalid.

Although we believe that our product candidates, production methods and other activities do not currently infringe the intellectual property rights of these and other third parties, we cannot be certain that a third party will not challenge our position in the future. If a third party alleges that we are infringing its intellectual property rights, we may need to obtain a license from that third party, but there can be no assurance that any such license will be available on acceptable terms or at all. Any infringement claim that results in litigation could result in substantial cost to us and the diversion of management's attention away from our core business and could also prevent us from marketing our products. To enforce patents issued to us or to determine the scope and validity of other parties' proprietary rights, we may also become involved in litigation or in interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial costs to us or an adverse decision as to the priority of our inventions. We may be involved in interference and/or opposition proceedings in the future. We believe there will continue to be significant litigation in the industry regarding patent and other intellectual property rights.

We are party to license agreements which provide us rights to use technologies in our research, development and commercialization of our product candidates. We obtained a non-exclusive license from Boyce Thompson Institute for Plant Research to use certain information and materials in the field of prevention and treatment of immune system diseases and disorders related to NHL. This party has sole responsibility for the prosecution, maintenance and enforcement of the licensed intellectual property.

We also rely on trade secrets to protect our technology, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We attempt to protect our trade secrets by requiring each of our employees, consultants and advisors to execute a non-disclosure and assignment of invention agreement before beginning his or her employment, consulting or advisory relationship with us. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party.

### **Government Regulation**

The testing, development, manufacturing, labeling, storage, record keeping, advertising, promotion, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical and biologic products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are regulated by the FDA as biologics. Biologics require the submission of a Biologics License Application, or BLA, and approval by the FDA prior to being marketed in the United States. None of our product candidates have been approved by the FDA for marketing in the United States, and we currently have no BLAs pending. Manufacturers of biologics may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us to administrative or judicial sanctions, including, but not limited to, FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines, injunction and criminal prosecution.

The steps required before a biologic may be approved for marketing in the United States generally include:

- completion of preclinical laboratory tests and animal tests;
- the submission to the FDA of an investigational new drug, or IND, application for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- the submission to the FDA of a BLA;
- FDA review of the BLA; and
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product candidate is made to assess compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations.

The testing and approval process typically takes several years and requires the commitment of substantial effort and financial resources. Despite the time and expense committed, there can be no assurance that any approval will be granted on a timely basis, or at all.

Preclinical tests include laboratory evaluation and animal studies to assess the pharmacology and toxicology of the product candidate. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time raises concerns or questions about the conduct of the trials as outlined in the IND, including concerns that human research subjects will be exposed to unreasonable risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. A separate submission to an existing IND must also be made for each successive clinical trial

conducted during product development. Further, each clinical trial must be reviewed and approved by an independent Institutional Review Board, or IRB.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics. Phase 2 usually involves studies in a limited patient population to (i) evaluate preliminarily the efficacy of the drug for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage and (iii) identify possible adverse effects and safety risks. Phase 3 clinical trials generally further evaluate clinical efficacy and test further for safety within an expanded patient population. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Furthermore, we, the FDA or the relevant IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of a BLA requesting approval to market the product. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the facility cGMP compliance is satisfactory. The FDA may deny a BLA if applicable regulatory criteria are not satisfied, require additional testing or information or require postmarketing testing and surveillance to monitor the safety or efficacy of a product. Approval entails limitations on the indicated uses for which a product may be marketed. Also, if we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, we will need FDA review and approval before the change can be implemented.

We are utilizing the procedure called "Special Protocol Assessment" for FavId. Under this procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except in limited circumstances. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. Although we received our SPA, there can be no assurance that any of our trials will have a successful outcome.

In December 2005, we received the FDA designation of FavId as a "fast track product" for treatment of patients with follicular B-cell NHL. We also intend to apply for "fast track" designation for FAV-201 for T-cell lymphoma. Fast track products are those which are intended for the treatment of a serious or life-threatening condition and which demonstrate the potential to address unmet medical needs for such conditions. Fast track products are eligible for two means of potentially expediting product development and FDA review of BLAs. First, a fast track product may be approved on the basis of either a clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. It is sometimes possible to demonstrate efficacy with respect to such endpoints in a shorter period of time than would be the case for other endpoints. Approvals of this kind may be subject to requirements for appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect of the clinical endpoint, and to certain other conditions. Second, if the FDA determines after review of preliminary clinical data submitted by the sponsor that a fast track product may be effective, it may begin review of portions of a BLA before the sponsor submits the complete BLA, thereby accelerating the date on which review of a portion of the BLA can begin. There can be no assurance that any of our product candidates in development will receive designation as fast track products, and even if they are designated as fast track products, there can be no assurance that our product candidates will be reviewed or approved more expeditiously than would otherwise have been the case.

We intend to request priority review of our BLA for FavId. A priority designation sets the target date for the FDA to complete review of a BLA within six months of the date of submission. Priority review of biologics is available for product candidates which, if approved, would be a significant improvement in the safety or effectiveness of the treatment of a serious or life-threatening disease. Even if priority review is granted, there can be no assurance that FDA review will be completed within six months or any other specific period of time, nor that the product candidate will be approved.

BLA holders must continue to comply with a number of FDA requirements both before and after approval. For example, BLA holders are required to report certain adverse reactions to the FDA and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations after approval, and the FDA periodically conducts inspections of manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, monies and effort in the area of production and quality control to maintain cGMP compliance. In addition, discovery of problems, such as safety problems,

may result in changes in labeling or restrictions on a product, manufacturer or BLA holder, including removal of the product from the market.

We plan to seek orphan drug designation for the use of FAV-201 for T-cell lymphoma. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. Our products may not be eligible for orphan drug status or be designated as orphan drugs. Even if designated as orphan drugs, our products may not be approved before other applications or granted orphan drug exclusivity if approved.

### **Third-Party Reimbursement**

We expect that sales volumes and prices of our products will be dependent in part on the availability of coverage and reimbursement from third-party payors. In the United States, such payors include governmental programs, including Medicare and Medicaid, private insurance plans and managed care programs. The Medicare program, a federally-funded and administered health insurance program, is the nation's single largest payor, and provides for coverage for certain medical products and services for certain aged and disabled individuals and individuals with end-stage renal disease. Significantly, other third-party payors often model their coverage and reimbursement policies after Medicare. Medicare and other third-party payors may deny coverage and reimbursement if they determine that a medical product or procedure is not medically necessary or used for an unapproved indication, among other things. There can be no assurance that a new product will be considered medically necessary or otherwise eligible for coverage and reimbursement. Our ability to earn sufficient returns on our products may depend in part on the extent to which adequate third-party reimbursement is available for the costs of such products and related treatments. Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products, and there can be no assurance that adequate third-party coverage and reimbursement will be available.

### **Fraud and Abuse Laws**

If we are able to commercialize FavId or any other product candidates that we may develop, we will be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. Healthcare fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a statute or prohibition has been violated. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations. In addition, some allegations under these laws have been claimed to violate the False Claims Act, discussed in more detail below.

In addition, if we are able to commercialize FavId or any other product candidates that we may develop, we could become subject to false claims litigation under federal statutes, which can lead to civil money penalties, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. These false claims statutes include the False Claims Act, which any person to bring suit on behalf of the federal government alleging the submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against biotechnology companies have increased significantly in recent years and have increased the risk that a healthcare company will have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action.

## Employees

As of December 31, 2006, we had 151 employees. Of these, 123 employees were in research and development comprised of 88 in manufacturing, quality control and quality assurance, 32 in research and process development, and three members of senior management. Of the remaining employees, three were members of senior management and 25 were in marketing, general and administration. As of the same date, 17 of our employees had a Ph.D., M.D. or Pharm.D. degree. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

## Reports

We make available free of charge through our website, [www.favrille.com](http://www.favrille.com), our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or to be furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Any information that is included on or linked to our Internet site is not a part of this report or any registration statement that incorporates this report by reference.

## Executive Officers and Directors of the Registrant

The following table sets forth information regarding our executive officers and directors as of March 1, 2007:

<u>Name</u>	<u>Age</u>	<u>Positions</u>
John P. Longenecker, Ph.D.....	59	President, Chief Executive Officer and Director
Tamara A. Seymour.....	48	Chief Financial Officer and Vice President, Finance and Administration
Daniel P. Gold, Ph.D. ....	52	Chief Scientific Officer
David L. Guy.....	44	Chief Commercial Officer
Richard Murawski.....	58	Senior Vice President, Operations
John F. Bender, Pharm.D.....	58	Senior Vice President, Clinical Research
Alice M. Wei.....	43	Vice President, Regulatory Affairs and Quality
Michael L. Eagle.....	59	Chairman of the Board of Directors
Cam L. Garner.....	58	Director
Antonio J. Grillo-Lopez, M.D. ....	67	Director
Peter Barton Hutt.....	72	Director
David Molowa.....	47	Director
Fred Middleton.....	57	Director
Arda Minocherhomjee, Ph.D. ....	53	Director
Wayne I. Roe.....	56	Director
Ivor Royston, M.D.....	61	Director

**John P. Longenecker, Ph.D.** has served as a member of our board of directors and as our President and Chief Executive Officer since February 2002. From March 1999 to February 2002, he served as President of SkyePharma, Inc. and was a member of the Executive Committee of SkyePharma PLC. In 1992, Dr. Longenecker joined DepoTech Corporation as its Senior Vice President of Research, Development and Operations and then served as its President and Chief Operating Officer from February 1998 to March 1999. From 1982 to 1992, he was at Scios, Inc. (now a Johnson & Johnson subsidiary), and served as its Vice President and Director of Development from 1986 to 1992. Dr. Longenecker received a bachelor's degree in Chemistry from Purdue University and a Ph.D. in Biochemistry from The Australian National University in Canberra, Australia.

**Tamara A. Seymour** has served as our Chief Financial Officer since May 2001 and also as our Vice President of Finance and Administration since February 2004. From 1991 to May 2001, she served as consulting chief financial officer for a number of biotechnology companies. Her client list included CancerVax Corporation (now Micromet Corporation), LXX Corporation, VitaGen Incorporated and Chromagen. From 1988 through 1991, Ms. Seymour was Director of Finance with Agouron Pharmaceuticals, Inc. between 1980 and 1988, she worked as an accountant with Deloitte & Touche LLP and Coopers & Lybrand, Inc. (now PricewaterhouseCoopers LLP). Ms. Seymour is a Certified Public Accountant and received a bachelor's degree in Business Administration with an emphasis in Accounting from Valdosta State University and an M.B.A. with an emphasis in Finance from Georgia State University.

**Daniel P. Gold, Ph.D.** co-founded Favrilite in January 2000, served as our Executive Vice President of Research and Development from January 2000 to July 2003 and has served as our Chief Scientific Officer since July 2003. He was an Associate Professor at the Sidney Kimmel Cancer Center in San Diego from 1992 through 2003. Dr. Gold received a bachelor's degree in Biology from the University of California, Los Angeles, and a Ph.D. in Immunology from Tufts Medical School.

**David L. Guy** joined Favrilite as our Chief Commercial Officer in December 2005. Prior to joining Favrilite, Mr. Guy served as Vice President, Global Strategic Marketing and Business Development, Oncology at Schering AG/Berlex from 2002 to 2005. Previously, he served as Director, Oncology Marketing at Genentech from 2000 to 2001. Prior to Genentech, Mr. Guy spent six years at Sanofi-Aventis as U.S. Business Unit Head, Oncology (Sanofi) from 1994 to 2000. Mr. Guy earned his Bachelor of Science degree in Biology with a specialization in Molecular Genetics from McMaster University in Hamilton, Ontario.

**Richard Murawski** has served as our Senior Vice President of Operations since June 2002. From June 1998 to May 2002, he was the Vice President of Global Biotech Operations of Baxter BioScience Corporation. In 1997 and 1998, he served as a consultant. Mr. Murawski was the Vice President of Operations of Cytogen from 1994 to 1997 and Director of Operations at Welgen (Wellcome) from 1990 to 1993. From 1971 to 1990, he served as Plant Manager for Schering-Plough. Mr. Murawski received a bachelor's degree in Chemical Engineering from the Newark College of Engineering.

**John F. Bender, Pharm.D.** served as our Vice President of Clinical Research from May 2001 through March 2005 and has served as our Senior Vice President of Clinical Research since March 2005. From 1981 to 2001, he was at Pfizer Global Research and Development (formerly Parke-Davis), a division of Pfizer, Inc., and served as its Director of Clinical Research-Oncology from 1997 to 2001. At Pfizer, Dr. Bender was involved with the development of over 20 oncology and infectious disease compounds. He received a bachelor's degree in Biology from Mount Saint Mary's College, a bachelor's degree in Pharmacy from the University of Maryland and a Pharm.D. from the University of Utah.

**Alice M. Wei** has served as our Vice President of Regulatory Affairs and Quality since October 2002. From 1993 to September 2002, she was at IDEC Pharmaceuticals Corporation (now Biogen Idec), most recently as Department Head/Senior Director of Regulatory Affairs. Ms. Wei was Director of Regulatory Affairs, Quality Assurance and Quality Control at Anesta Corp. (now Cephalon, Inc.) from 1990 through 1993 and served in various regulatory positions at Immunotech Pharmaceuticals (now Elan Pharmaceuticals) and ICN Pharmaceuticals, Inc. (now Valeant Pharmaceuticals) from 1984 to 1990. She received a bachelor's degree in Microbiology/Chemistry from the University of Texas at Arlington.

**Michael L. Eagle** has served as a member of our board of directors since September 2003 and as Chairman since September 2006. He was Vice President-Manufacturing for Eli Lilly and Company from 1993 to April 2001. Mr. Eagle is a founding member of Barnard Life Sciences and currently serves as a member of the board of a number of privately-held companies. Mr. Eagle received a bachelor's degree in Engineering from Kettering University and an M.B.A. from the Krannert School of Management at Purdue University.

**Cam L. Garner** has served as a member of our board of directors since December 2000, served as Chairman of our board of directors from May 2001 through September 2006, and served as our acting Chief Executive Officer from August 2001 to February 2002. Mr. Garner co-founded specialty pharmaceutical companies, Verus Pharmaceuticals, Inc., Cadence Pharmaceuticals, Inc., Zogenix, Inc., DJ Pharma and Xcel Pharmaceuticals, Inc. He serves as Chairman and CEO of Verus, Chairman of Cadence and Zogenix and served as Chairman of Xcel until it was acquired in 2005 by Valeant Pharmaceuticals International. He was Chief Executive Officer of Dura Pharmaceuticals, Inc., a pharmaceutical company, from 1989 to 1995 and its Chairman and Chief Executive Officer from 1995 to 2000 until it was sold to Elan in November 2000. Mr. Garner also serves on the board of directors of Pharmion Corp., Somaxon Pharmaceuticals, Inc., SkinMedica, Inc. and Aegis Therapeutics. Mr. Garner earned his M.B.A. from Baldwin-Wallace College and his B.A. in Biology from Virginia Wesleyan College.

**Antonio J. Grillo-Lopez, M.D.** has served as a member of our board of directors since January 2001. He was Chief Medical Officer and Senior Vice President of Medical and Regulatory Affairs at IDEC Pharmaceuticals Corporation (now Biogen Idec) from 1992 to January 2001. Prior to 1992, Dr. Grillo-Lopez served as Executive Medical Director for International Clinical Research Development at DuPont Merck Pharmaceutical Co. and as Vice President of Clinical Therapeutics and Director of Clinical Oncology Research at Parke-Davis (now Pfizer). From 1980 to 1990, he was at the University of Michigan, most recently as an Associate Professor of Medicine. Dr. Grillo-Lopez currently serves as a director of Onyx Pharmaceuticals, Inc., a biopharmaceutical company. He received a bachelor's degree in Natural Sciences from the

University of Puerto Rico, College of Natural Sciences, and an M.D. from the University of Puerto Rico School of Medicine.

**Peter Barton Hutt** has served as a member of our board of directors since November 2003. Mr. Hutt has been a partner or senior counsel specializing in food and drug law in the Washington, D.C. law firm of Covington & Burling since 1968, except when he served as Chief Counsel for the FDA from 1971 to 1975. He is the co-author of a casebook used to teach food and drug law throughout the country and teaches a full course on this subject each year at Harvard Law School. Mr. Hutt currently serves on the board of directors of CV Therapeutics, Inc., a biopharmaceutical company, ISTA Pharmaceuticals, Inc., a specialty pharmaceutical company, Momenta Pharmaceuticals, Inc., a biotechnology company, Xoma, a biotechnology company, Introgen Therapeutics, Inc., a biopharmaceutical company, and privately-held biopharmaceutical companies and on venture capital advisory boards, including Polaris Venture Partners and the Sprout Group. Mr. Hutt received a bachelor's degree in Economics and Political Science from Yale University, an LL.B. from Harvard Law School and an L.L.M. in Food and Drug Law from New York University Law School.

**David Molowa Ph.D.** was appointed to our Board of Directors in July 2006. Since September 2006, Dr. Molowa has been a partner of Venrock Associates. Prior to joining Venrock Associates, Dr. Molowa was Managing Director of life science equity research at UBS Securities from 2004 to 2006 and Managing Director of life science equity research at JP Morgan from 2000 to 2004. From 1991 to 2000, Dr. Molowa was Senior Managing Director of biotechnology equity research at Bear Stearns & Co. Previous to his career in the financial industry, Dr. Molowa was a senior research biochemist for Merck & Co. He received a bachelor's degree in Biology from the University of Richmond, Ph.D. in Pharmacology/Toxicology from the Medical College of Virginia and an M.B.A. from Rutgers University.

**Fred Middleton** has served as a member of our board of directors since May 2002. Since 1987, he has been a General Partner/Managing Director of Sanderling Ventures, a firm specializing in biomedical venture capital, and an affiliate of certain holders of our capital stock. From 1984 through 1986, he was Managing General Partner of Morgan Stanley Ventures, an affiliate of Morgan Stanley & Co. Prior to that, from 1978 to 1984, Mr. Middleton served as Vice President of Finance and Corporate Development, Chief Financial Officer, and President of Genentech Development Corporation for Genentech, Inc. He currently serves as Chairman of the Board of Stereotaxis, Inc., a biotechnology company, and also as a director of several privately-held companies. Mr. Middleton received a bachelor's degree in Chemistry from the Massachusetts Institute of Technology and an M.B.A. with distinction from Harvard Business School.

**Arda Minocherhomjee, Ph.D.** has served as a member of our board of directors since March 2004. He is currently a partner of Chicago Growth Partners. Since 1992, Dr. Minocherhomjee has served in various capacities for William Blair & Company, L.L.C., an affiliate of certain holders of our capital stock, including, most recently, as a Principal. Since September 1998, Dr. Minocherhomjee has also served as a managing member of William Blair Capital Partners, an affiliate of William Blair & Company, L.L.C. He currently serves on the board of directors of CryoCor Inc., a medical device company, as well as several privately-held pharmaceutical and medical device companies. Dr. Minocherhomjee received a master's degree in Pharmacology from the University of Toronto and a Ph.D. and an M.B.A. from the University of British Columbia, and was a post-doctoral fellow in Pharmacology at the University of Washington Medical School.

**Wayne I. Roe** has served as a member of our board of directors since February 2001. He was the founding Chief Executive Officer and Chairman of Covance Health Economics and Outcomes Services, Inc. from 1988 to 1999 and previously served as Vice President for Economic and Health Policy for the Health Industry Manufacturers Association. He currently sits on the boards of directors of Aradigm Corporation, a biopharmaceutical company, ISTA Pharmaceuticals, Inc., a specialty pharmaceutical company, and a number of privately-held companies. Mr. Roe also serves on the executive committee of the Maryland Angels Fund. Mr. Roe received a bachelor's degree in Economics from Union College and an M.A. in Economics from the University of Maryland.

**Ivor Royston, M.D.** has served as a member of our board of directors since January 2000, and as our acting Chief Executive Officer from January 2000 to August 2001. He is a co-founder of Forward Ventures, a venture fund affiliated with certain holders of our capital stock. From 1990 to 2000, Dr. Royston served as the founding President and Chief Executive Officer of the non-profit Sidney Kimmel Cancer Center. He remains a member of the Board of Trustees of that organization. In 1986, Dr. Royston co-founded IDEC Pharmaceuticals Corporation (now Biogen Idec), and in 1978 he founded Hybritech, Inc. From 1978 to 1990, Dr. Royston served on the faculty of the medical school and cancer center at the University of California, San Diego. Dr. Royston also serves on the board of directors of CancerVax Corporation, a biotechnology company, Corautus Genetics, Inc., a biopharmaceutical company and Avalon Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Royston received a bachelor's degree in Human Biology and an M.D. from The Johns Hopkins University and completed post-doctoral training in internal medicine and medical oncology at Stanford University.

## **Item 1A. Risk Factors**

*You should consider carefully the risk factors described below, together with the other information contained in this report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.*

### **Risks Related to the Development of Our Product Candidates**

#### **Failure to obtain product approvals by the FDA could harm our business.**

We are subject to rigorous and extensive regulation by the FDA. In the United States, our biologic product candidates, currently in the preclinical and clinical stages of development, cannot be marketed until they are approved by the FDA. Obtaining FDA approval involves the submission of the results of preclinical studies and clinical trials of the product candidates, among other information. We may not be able to obtain FDA approval, and, even if we are able to do so, the approval process typically takes many years and requires the commitment of substantial effort and financial resources. The FDA can delay, limit or deny approval of a biologic product candidate for many reasons, including:

- the FDA may not find that the biologic product candidate is sufficiently safe or effective;
- FDA officials may interpret data from preclinical testing and clinical trials differently than we do; and
- the FDA may not find our manufacturing processes or facilities satisfactory.

In addition, the specific active immunotherapy technology on which FavId is based is a relatively new form of cancer therapy that presents novel issues for the FDA to consider, which may make the regulatory process especially difficult.

We cannot assure you that any of our product candidates in development will be approved in the United States in a timely fashion, or at all. Failure to obtain regulatory approval of our product candidates in a timely fashion, or at all, would prevent or delay us from marketing or selling any products and, therefore, from generating revenues from their sale. If this occurs, we may be unable to generate sufficient revenues to attain or maintain profitability, our ability to raise additional capital will be impaired and our stock price may be negatively affected. In addition, both before and after approval, we are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion and export of biologics. Failure to comply with the law, including statutes and regulations, administered by the FDA, could result in, among others, any of the following actions:

- warning letters;
- fines and other civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve a product candidate;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

**We are dependent on the success of our lead product candidate, FavId, and we cannot be certain that it will be commercialized.**

We have expended significant time, money and effort in the development of our lead product candidate, FavId, which is still in clinical development, has not yet received regulatory approval and may never be commercialized. In order to commercialize FavId, we will need to demonstrate to the FDA and other regulatory agencies that it satisfies rigorous standards of safety and effectiveness. We completed patient enrollment in a pivotal Phase 3 clinical trial of FavId following Rituxan for the treatment of follicular B-cell NHL in January 2006.

We are also evaluating FavId for use in other B-cell NHL indications. However, even if we were to receive regulatory approval of FavId for the treatment of follicular B-cell NHL or the other indications we are exploring, our ability to successfully commercialize FavId could be jeopardized by the emergence of a competitive product that exhibits greater efficacy, longer duration of response or other benefits. In addition, because our initial regulatory and marketing strategy contemplates the administration of FavId to patients following treatment with Rituxan, the commercial opportunity for FavId may be limited by the degree to which oncologists continue to use Rituxan to treat indolent B-cell NHL. Furthermore, to the extent FavId fails to gain market acceptance for its initial indication, it may be more difficult for us to generate sufficient credibility with physicians and patients to commercialize FavId for other indications.

Other than FavId, we have only two other product development programs, which are at significantly earlier stages of development. In June 2006, we received an allowance from the FDA for an IND for a product candidate, FAV-201, from one of these programs for the treatment of cutaneous T-cell lymphoma. We have ongoing preclinical studies to assess the applicability of our technology to autoimmune diseases, with an initial focus on multiple sclerosis. We cannot be certain that we will be able to successfully develop any product candidate from these development programs. We cannot be certain that the clinical development of FavId or any other product candidate in preclinical testing or clinical trials will be successful, that it will receive the regulatory approvals required to commercialize it, or that any of our other research programs will yield a product candidate suitable for entry into clinical trials. If we are unable to commercialize FavId or our other product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, our ability to raise additional capital will be impaired and our stock price may be negatively affected.

**Before we can seek regulatory approval of any of our product candidates, we must successfully complete clinical trials, which are uncertain.**

Conducting clinical trials is a lengthy, time-consuming and expensive process, and the results of these trials are inherently uncertain. We have completed enrollment of patients in several Phase 2 clinical trials of FavId involving over 130 indolent B-cell NHL patients and are currently conducting follow-up evaluation of those patients. We completed enrollment of patients in a pivotal double-blind, placebo controlled Phase 3 clinical trial of FavId for the treatment of follicular B-cell NHL in January 2006 with 349 randomized patients. During the week of November 6, 2006, our Data Monitoring Committee completed a planned interim analysis of data from the secondary endpoint, overall response improvement, in the first 226 patients enrolled in the trial. The independent Data Monitoring Committee concluded that the interim analysis did not demonstrate a statistically significant difference between treatment and control groups in the secondary endpoint. We anticipate the final analysis of the primary endpoint, TTP, during the fourth quarter of 2007.

Four additional Phase 2 clinical trials of FavId are ongoing. One of these clinical trials is being conducted under a separate physician-sponsored IND in the United States. In June 2006, we received an allowance from the FDA for an IND for our second product candidate, FAV-201, for the treatment of cutaneous T-cell lymphoma.

We have received a Special Protocol Assessment, or SPA, from the FDA for our pivotal Phase 3 clinical trial of FavId. In the SPA process, the FDA reviewed the design, size and planned analysis of our Phase 3 clinical trial and provided comments regarding the trial's adequacy to form a basis with respect to effectiveness for approval of a Biologics Licensing Application, or BLA, if the trial meets its predetermined objectives. We will not be able to file a BLA for FavId until after we receive an analysis of the primary endpoint, TTP, of our ongoing pivotal Phase 3 clinical trial (assuming the TTP data is positive), which analysis is anticipated in the fourth quarter of 2007, or at all. The FDA's written agreement is binding, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety or effectiveness of a product candidate is identified after the Phase 3 clinical trial is commenced. Despite having received an SPA, we may be required to conduct an additional Phase 3 clinical trial of FavId for the treatment of indolent B-cell NHL before we can apply for regulatory approval. Although the FDA typically requires successful results in two Phase 3 clinical trials to support marketing approval, the FDA has, on several occasions, approved products based on a single Phase 3 clinical trial that

demonstrates a high level of statistical significance where there is an unmet need for a life-threatening condition. We currently plan to seek FDA approval of FavId based on our ongoing pivotal Phase 3 clinical trial alone. In the event that the FDA requires the results of a second Phase 3 clinical trial before accepting a BLA or before granting marketing approval of FavId, our launch of FavId would be delayed, possibly by several years, and we would incur significant costs in conducting the additional trial.

The preliminary, blinded clinical data reported from time to time prior to the release of the final results of our pivotal Phase 3 clinical trial and the preliminary clinical data from our Phase 2 clinical trials have not been fully audited and have been taken from databases that have not been fully reconciled against medical records kept at the clinical sites or that may not include the most current information on patient disease progressions. The data released may not be indicative of the final results of our pivotal Phase 3 clinical trial or any other clinical trial of FavId. Failure can occur at any stage of testing. We do not know whether our Phase 3 clinical trial or any future clinical trials will demonstrate safety and efficacy sufficient to result in marketable products. Our failure to adequately demonstrate the safety and efficacy of FavId will prevent us from obtaining regulatory approval for, or commercializing, FavId.

Completion of necessary clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of the product candidate, or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;
- delay or failure in obtaining approval of our clinical trial protocols from the FDA;
- slower than expected rate of patient recruitment and enrollment;
- inability to adequately follow and monitor patients after treatment;
- difficulty in managing multiple clinical sites;
- unforeseen safety issues; and
- government or regulatory delays.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial or require us to conduct additional trials. Our clinical trials may be suspended at any time for a variety of reasons, including if the FDA or we believe the patients participating in our trials are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

**Failure to enroll patients in our clinical trials may cause delays in developing FavId or any other product candidate.**

We may encounter delays in development and commercialization, or fail to obtain marketing approval, of FavId or any other product candidate that we may develop if we are unable to enroll enough patients to complete clinical trials. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial and competing clinical trials. Although we completed patient enrollment in our pivotal Phase 3 clinical trial of FavId in January 2006, we have from time to time experienced slower-than-expected patient enrollment in our clinical trials and may do so in the future if additional clinical trials of FavId are required or if we clinically develop any of our other product candidates.

Delays in planned patient enrollment may result in increased costs and harm our ability to complete our clinical trials and obtain regulatory approval.

**The development of FavId requires the continued availability of two FDA-approved drugs: GM-CSF and Rituxan.**

Administration of FavId requires an adjuvant, which is a substance that is used to enhance the immune response. We use a white blood cell growth factor known as GM-CSF, which is commercially available solely from Berlex Laboratories, Inc., as an adjuvant for FavId. GM-CSF is an FDA-approved and commercially available drug that may be purchased by physicians. In February 2007, we entered into a clinical supply and study agreement with Berlex for clinical trials of FavId performed in the United States, prior to which time we relied on purchase orders to purchase GM-CSF from Berlex. If we require GM-CSF for use in clinical trials outside the United States, or for use in other clinical trials not covered by our agreement with Berlex, we will need to rely on purchase orders for such purchases. Our current strategy for the initial commercialization of FavId involves the administration of FavId following treatment with Rituxan. Rituxan is a passive immunotherapy for patients with NHL, which is also FDA-approved and is commercially available solely from Genentech, Inc. and Biogen Idec Inc. We currently rely on physicians to order and administer Rituxan to patients prior to the administration of FavId in our registration trial. If GM-CSF or Rituxan were to become unavailable as a result of regulatory actions, supply constraints or other reasons, our ability to continue the clinical development of FavId would be jeopardized.

**Risks Related to Our Financial Results and Need for Financing**

**We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial losses and negative cash flow from operations for the foreseeable future.**

We are a development stage company with a limited operating history. We have financed our operations through private placements of common stock and warrants, an initial public offering of our common stock and equipment and leasehold debt financing. We have incurred losses in each year since our inception in 2000. Net losses applicable to common stockholders were \$40.5 million, \$35.9 and \$54.2 million for the years ended December 31, 2006, 2005 and 2004, respectively. As of December 31, 2006, we had an accumulated deficit of \$155.9 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to incur substantial operating losses for at least the next several years. This is due primarily to the expansion of our clinical trials and research and development programs, preparations to manufacture FavId on a commercial scale, and, selling, general and administrative expenses. We also have substantial lease and debt obligations related to our new manufacturing and headquarters facilities impacting our operating expenses. We expect that our losses will fluctuate from quarter to quarter and that these fluctuations may be substantial. We cannot guarantee that we will successfully develop, manufacture, commercialize or market any products. As a result, we cannot guarantee that we will ever achieve or sustain product revenues or profitability.

**We currently have no source of revenue and may never become profitable.**

Our ability to become profitable will depend upon our ability to generate revenue. To date, FavId has not generated any revenue, and we do not know when or if FavId will generate revenue. Our ability to generate revenue depends on a number of factors, including our ability to:

- successfully complete clinical trials for FavId;
- obtain regulatory approval for FavId, including regulatory approval for our commercial scale manufacturing facility and process;
- manufacture commercial quantities of FavId at acceptable cost levels; and
- successfully market and sell FavId.

We do not anticipate that we will generate revenues until 2008, at the earliest. Further, we do not expect to achieve profitability for at least several years after generating material revenues. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

**We will need substantial additional funds to continue operations, which we may not be able to raise on favorable terms, or at all.**

We will need substantial additional funds for existing and planned preclinical studies and clinical trials, to continue research and development activities, for lease and debt obligations related to our manufacturing and headquarter facilities, and to establish manufacturing and marketing capabilities for any products we may develop. In addition, because we do not expect to generate revenues from the sale of our product candidates for several years, if at all, we will also need to raise additional capital to fund our operations.

We believe that our cash, cash equivalents and short-term investments, which was approximately \$42.4 million at December 31, 2006, together with the \$10 million raised in an equity financing in February 2007 and access to the Committed Equity Financing Facility, or CEFF, through Kingsbridge Capital Limited, will be sufficient to meet our projected operating requirements at least for the next 12 months. We will need to raise additional funds in order to commercialize FavId, including the completion of the expansion and qualification of our manufacturing facility for commercial-scale production. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this prospectus. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Our future capital requirements or the adequacy of our available funds will depend on many factors, including, but not limited to:

- the results of our ongoing pivotal Phase 3 clinical trial of FavId;
- magnitude and cost of our product development efforts and other research and development activities;
- rate of progress toward obtaining regulatory approval for our product candidates;
- costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- our ability to establish and maintain collaborative, licensing or other arrangements for the development, sale, marketing or distribution of our product candidates and the terms of those arrangements;
- effects of competing technological and market developments;
- the cost of expansion of our current facility for commercial production or the construction of a large separate commercial-scale production facility; and
- the success of the commercialization of FavId.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

To that end, on June 20, 2006, we filed a shelf registration statement with the SEC on Form S-3 pursuant to which we may periodically sell up to \$60 million in debt securities, common stock or warrants to purchase debt securities or common stock. In February 2007, we sold \$10 million of common stock pursuant to the shelf registration statement. Additionally, we have entered into the CEFF pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to \$40.0 million of our common stock. We may seek to access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Additional funding may not be available to us, and, if available, may not be on acceptable terms. If we raise additional funds by issuing equity securities, stockholders will incur immediate dilution. If adequate funds are not available to us, we may be required to delay, reduce the scope of, or eliminate one or more of our research, development and clinical activities. Alternatively, we may need to seek funds through arrangements with collaborative partners or others that require us to relinquish rights to technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. Any of these events could have a material adverse effect on our business, results of operations, financial condition or cash flow.

**Our committed equity financing facility with Kingsbridge may not be available to us if we elect to make a draw down, may require us to make additional “blackout” or other payments to Kingsbridge and may result in dilution to our stockholders.**

In December 2006, we entered into the CEFF with Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of 36 months, shares of our common stock for cash consideration up to an aggregate of \$40.0 million, subject to specified conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; and the effectiveness of a registration statement registering for resale the shares of common stock to be issued in connection with the CEFF. In addition, among other termination rights, Kingsbridge is permitted to terminate the CEFF by providing written notice to us within 10 business days after it obtains actual knowledge that an event has occurred resulting in a material and adverse effect on our business, operations, properties or financial condition (subject to specified exceptions, including conditions or events that are reasonably expected to occur in the ordinary course of our business). If we are unable to access funds through the CEFF, or if Kingsbridge terminates the CEFF, we may be unable to access capital on favorable terms, or at all.

We are entitled, in certain circumstances, to deliver a “blackout” notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus for a certain period of time. If we deliver a blackout notice in the 75 trading days following the settlement of a draw down and the volume weighted average price on the trading day immediately preceding the related blackout period is greater than the volume weighted average price on the first trading day following such blackout period, or if the registration statement of which this prospectus is a part is not effective in circumstances not permitted by our registration rights agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by Kingsbridge immediately prior to the blackout period and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our stock price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining stock price will have an even greater dilutive effect than if our stock price were stable or increasing and may further decrease our stock price.

**Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected revenue or expense fluctuations and affect our reported results of operations.**

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, in December 2004, the FASB issued SFAS No. 123(R), “Share-Based Payment,” which is a revision of SFAS No. 123, “Accounting for Stock-Based Compensation.” In April 2005, the SEC approved a vote that effectively required us to adopt this statement on January 1, 2006. This statement eliminates the ability to account for stock-based compensation using the intrinsic value method allowed under APB 25 and requires these transactions to be recognized as compensation expense in the statement of operations based on the fair values on the date of grant, with the compensation expense recognized over the period in which an employee or director is required to provide service in exchange for the stock award. This new requirement will result in an increase in our stock-based compensation expense, which will increase our net losses. For example, as a result of adopting SFAS 123(R), the Company’s net loss for the year ended December 31, 2006 is approximately \$1.3 million larger, than if the Company had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share for year ended December 31, 2006 is \$0.05 higher than if the Company had continued to account for stock-based compensation under APB 25.

## Other Risks Related to Our Business and Industry

**We currently depend on single source suppliers for critical raw materials for manufacturing. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of FavId.**

We currently depend on single source suppliers for critical raw materials used in the manufacture of FavId. In particular, our manufacturing process for FavId requires a foreign protein derived from shellfish that is known as keyhole limpet hemocyanin, or KLH. We purchase KLH from biosyn Arzneimittel GmbH, or biosyn, which is currently the only supplier of KLH that has submitted the required filing, known as a drug master file, to the FDA. In November 2004, we entered into an eight-year supply and license agreement with biosyn under which biosyn has agreed to supply us with KLH and we have committed to annual KLH purchase requirements during the commercialization of FavId. In October 2006, we made a payment of \$50,000 to biosyn for the achievement of a milestone. An additional aggregate of up to \$250,000 will be due upon the achievement of certain milestones, the timing of which is not known at this time. Either party may terminate the supply agreement upon a breach by the other party that is not cured within 60 days or other events relating to insolvency or bankruptcy. If we identify another supplier of KLH of suitable quality for our purposes, we will not be able to use the supplier as a second source of KLH for the commercial manufacture of FavId unless the KLH is tested to be comparable to the existing KLH.

In addition, we depend on a single source supplier for the cell growth media we use to produce FavId. We purchase this material from Expression Systems LLC, which in turn obtains several of the components used in the cell growth media from sole suppliers. We currently rely on purchase orders to obtain this material and do not have a supply agreement with Expression Systems. We intend to qualify a second source for the cell growth media or manufacture the cell growth media in-house from commercially available raw materials but may not be able to do so.

Establishing additional or replacement suppliers for these materials may take a substantial amount of time. In addition, we may have difficulty obtaining similar materials from other suppliers that are acceptable to the FDA. If we have to switch to a replacement supplier, we may face additional regulatory delays and the manufacture and delivery of FavId, or any other product candidates that we may develop, could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization. If we are unable to obtain adequate amounts of these materials, our clinical trials will be delayed. In addition, we will be required to obtain regulatory clearance from the FDA to use different materials that may not be as safe or as effective. As a result, regulatory approval of FavId, or any other product candidates that we may develop, may not be received at all.

**We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed or may not be able to obtain regulatory approval for or commercialize FavId or any other product candidates that we may develop.**

Our pivotal Phase 3 clinical trial of FavId for the treatment of follicular B-cell NHL is being conducted at 67 centers in the United States and will require long-term follow up of at least 342 patients randomized into the trial. One clinical trial of FavId is being conducted under the direction of a physician sponsor, rather than under our supervision. We do not have the ability to independently conduct clinical trials for FavId, or any other product candidate that we may develop, and we must rely on third parties, such as medical institutions and clinical investigators, including physician sponsors, to conduct our clinical trials. In particular, we will rely on these parties to recruit and enroll patients in our clinical trials. We also rely on third-party couriers to transport patient tissue samples and FavId. If any of the third parties upon whom we rely to conduct our clinical trials or transport patient tissue samples and immunotherapies do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, and need to be replaced, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by medical institutions and clinical investigators, including physician sponsors and other third-party vendors involved in data management, is compromised due to their failure to adhere to applicable laws or our clinical protocols or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize FavId, or any other product candidates that we may develop. If any of our relationships with any of these organizations or individuals terminates, we believe that we would be able to enter into arrangements with alternative third parties. However, replacing any of these third parties would delay our clinical trials and could jeopardize our ability to commercialize FavId and our other product candidates on a timely basis, or at all.

**Even if we obtain regulatory approval, we will continue to be subject to extensive government regulation that may cause us to delay the introduction of our products or withdraw our products from the market.**

Even if we obtain regulatory approval for FavId or our other product candidates, we will still be subject to extensive regulation. These regulations will impact many aspects of our operations, including production, record keeping, quality control, adverse event reporting, storage, labeling, advertising, promotion and personnel. In addition, the later discovery of previously unknown problems may result in restrictions of the product candidates, including their withdrawal from the market. Furthermore, regulatory approval may subject us to ongoing requirements for post-marketing studies. If we or any third party that we involve in our operations fail to comply with any continuing regulations, we may be subject to, among other things, product seizures, recalls, fines or other civil penalties, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

**Before we can obtain marketing approval for or commercially distribute FavId, we must have a commercial-scale facility for the manufacture of FavId. In addition, the FDA and the California Department of Health Services must find our manufacturing facility and process satisfactory.**

Our manufacturing methods, equipment and processes must comply with the FDA's current Good Manufacturing Practices, or cGMP, requirements. We may also need to perform extensive audits of vendors, contract laboratories and suppliers. The cGMP requirements govern, among other things, record keeping, production processes and controls, personnel and quality control. We have only undertaken initial steps towards achieving compliance with these regulatory requirements. Additional steps will require expenditure of significant time, money and effort. We cannot predict the likelihood that the FDA will find our facility satisfactory, even if we believe that we have taken the necessary steps to achieve compliance. If we fail to comply with these requirements or fail to pass a pre-approval inspection of our manufacturing facility in connection with an application to obtain marketing approval for FavId or another product candidate, we would not receive regulatory approval, and we would be subject to possible regulatory action.

We manufacture FavId for our ongoing pivotal Phase 3 and for the planned and ongoing Phase 2 clinical trials at our facility in San Diego. We currently lease an 80,000 square foot facility in San Diego, California under a long-term lease agreement. Our manufacturing facility consists of approximately 26,000 square feet of space in the facility. Our manufacturing facility is subject to the licensing requirements of the California Department of Health Services. Our facility was inspected and licensed by the California Department of Health Services. Our facility is subject to re-inspection at any time. Failure to maintain a license from the California Department of Health Services or to meet the inspection criteria of the California Department of Health Services would disrupt our manufacturing processes and prevent us from supplying FavId to patients. If an inspection by the California Department of Health Services indicates that there are deficiencies in our manufacturing process, we could be required to take remedial actions at potentially significant expense, and our facility may be temporarily or permanently closed.

We will need to either expand and qualify our current facility or construct and qualify a commercial scale manufacturing facility in order to commercialize FavId or any other product candidates that we may develop. We believe our current facility could be used to manufacture FavId for initial commercial launch, and we began construction to expand this facility during the second quarter of 2006. We cannot assure you that we would be able to meet commercial demand for FavId in this facility. Additionally, we may require a larger production facility to meet the demand for FavId if it is approved. We would need to raise additional debt or equity capital to finance construction of the larger facility. Such financing may not be available or, if available, may not be obtained on terms favorable to us or our stockholders.

Preparing a facility for commercial manufacturing may involve unanticipated delays and the costs of complying with FDA regulations may be significant. In addition, any material changes we make to the manufacturing process after approval may require approval by the FDA and state regulatory authorities. Obtaining these approvals is a lengthy, involved process, and we may experience delays that could limit our ability to manufacture commercial quantities, increase our costs and adversely affect our business.

**We may experience difficulties in manufacturing FavId or any other product candidates that we may develop, which could prevent us from completing our ongoing clinical trials and commercializing these product candidates.**

Manufacturing FavId is a complex, multi-step process that requires us to expend significant time, money and effort in production, record keeping and quality systems to assure that FavId will meet product specifications and other regulatory requirements. To date, we have manufactured FavId only for use in Phase 2 and Phase 3 clinical trials and have no experience in manufacturing FavId for the commercial quantities that might be required if we receive regulatory approval. In particular, we cannot be sure that we will be able to manufacture FavId at a cost that would enable commercial use. We may experience any of the following problems in our efforts to manufacture our product candidates for our expanding clinical trials or on a commercial scale:

- failure to obtain a sufficient supply of key raw materials;
- difficulties in completing the development and validation of the specialized assays required to ensure the consistency of our product candidates, including FavId;
- difficulties in obtaining adequate tumor samples from treating physicians and hospitals;
- difficulties in manufacturing FavId for multiple patients simultaneously;
- difficulties in the timely shipping of tumor samples to us or in the shipping of FavId to the treating physicians due to errors by third-party couriers, transportation restrictions or other reasons;
- failure to ensure adequate quality control and assurance in the manufacturing process as we increase the production quantities of FavId;
- difficulties in establishing and effectively managing a commercial-scale manufacturing facility;
- failure to comply with regulatory requirements, such as FDA regulations and environmental laws;
- significant changes in regulatory requirements;
- damage to or destruction of our manufacturing facility or equipment;
- difficulty in qualifying a second-source supplier for certain critical equipment; and
- shortages of qualified personnel.

In addition, because our manufacturing process only begins upon our receipt of a patient's tumor biopsy, we cannot produce inventory reserves of our product candidate to be stored in anticipation of any of these potential manufacturing problems. The failure to produce an adequate supply of FavId could delay our clinical trials and, in turn, delay submission of a BLA for FavId and commercial launch. Similarly, any difficulties we experience in the manufacture and supply of other product candidates, such as FAV-201, would delay the clinical trials of those product candidates.

**If our manufacturing facility is damaged or destroyed, our ability to manufacture products will be significantly affected, which could delay or prevent completion of our clinical trials and commercialization of FavId or any other product candidates that we may develop.**

We currently rely on the availability and condition of our manufacturing facility in San Diego to manufacture FavId. We lease the property where this facility is located under a lease agreement that expires June 30, 2025, but may be extended at our option for two additional five-year periods. After that time, we may not be able to negotiate a new lease for our facility. If the facility or our equipment in the facility is damaged or destroyed, we will not be able to quickly or inexpensively replace our manufacturing capacity. This would significantly affect our ability to complete clinical trials of, and to manufacture and commercialize, FavId, or any other product candidates that we may develop.

In addition, our facilities have been subject to electrical blackouts as a result of a shortage of available electrical power. Although we have back-up emergency power generators to cover energy needs for key support systems, a lengthy outage could disrupt the operations of our facilities and clinical trials. While we carry business interruption insurance, this insurance may not be adequate. Any significant business interruption could cause delays in our product development and harm our business.

**If we do not develop a sufficient sales and marketing force or enter into agreements with third parties to sell and market FavId, we may not be able to successfully commercialize our products, which would limit our ability to earn product revenues.**

We plan to retain exclusive worldwide rights to FavId for oncology indications at least until we receive the results from the pivotal Phase 3 clinical trial. If we are successful in obtaining BLA approval or foreign marketing approval for FavId, we will need to establish sales and marketing capabilities. In the United States, we plan to do this either by establishing our own sales force or by entering into a co-promotion arrangement with a sales and distribution partner. Outside of the United States, we plan to establish strategic collaborations for the development and marketing of FavId.

We do not presently possess the resources or experience necessary to market FavId or our other product candidates ourselves, and we currently have no arrangements for the promotion or distribution of our product candidates. Our future commercial success will depend on our ability to establish our own sales and marketing infrastructure or to collaborate with third parties that have greater sales and marketing experience and resources. Developing effective internal sales and marketing capabilities, which would include the hiring of a sales force, would require a significant amount of our financial resources and time.

We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, or at all, and any sales force we do establish may not be capable of generating demand for FavId or any other product candidate we may develop. In addition, if we cannot enter into co-promotion arrangements in the United States, or other strategic collaborations for the development and marketing of FavId in other countries, in a timely manner and on acceptable terms, we may not be able to successfully commercialize FavId or any other product candidate that we may develop.

To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we directly marketed and sold FavId, or any other product candidates that we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we will not be able to generate product revenue and will not become profitable.

**If physicians and patients do not use any of our products that may be approved, our ability to generate revenue in the future will be limited.**

If approved, FavId and other product candidates that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Demand for any approved product that we may develop will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- convenience and ease of administration;
- availability of alternative treatments;
- cost effectiveness;
- continuing widespread use of Rituxan to treat our initial target disease market;
- effectiveness of our regulatory and marketing strategies;
- prevalence and severity of adverse side effects;
- publicity concerning our products or competitive products; and

- our ability to obtain third-party coverage or reimbursement.

Furthermore, to the extent FavId fails to gain market acceptance for its initial indication, it may be more difficult for us to generate sufficient credibility with physicians and patients to commercialize FavId for other indications.

**If we are unable to obtain acceptable prices or adequate coverage and reimbursement from third-party payors for FavId, or any other product candidates that we may develop, our revenues and prospects for profitability will suffer.**

Our ability to commercialize FavId, or any other product candidates that we may develop, depends on the extent to which coverage and reimbursement for FavId, or any other product candidates that we may develop, will be available from:

- governmental payors, such as Medicare and Medicaid;
- private health insurers, including managed care organizations; and
- other third-party payors.

Many patients will not be capable of paying for FavId, or any other product candidates that we may develop, themselves and will rely on third-party payors to pay for their medical needs. The federal and state governments, insurance companies, managed care organizations and other third-party payors are actively seeking to contain or reduce costs of health care in the United States and exert increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are scrutinizing newly approved medical products and services and may not cover or may limit coverage and reimbursement for our product candidates. In particular, third-party payors may limit the indications for which they will reimburse patients who use FavId, or any other product candidates that we may develop. Cost-control initiatives could cause us to decrease the price we might establish for FavId, or any other product candidates that we may develop, which would result in lower product revenues. If the prices for FavId, or any other product candidates that we may develop, decrease or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels for FavId, or any other product candidates that we may develop, our revenue and prospects for profitability will suffer.

**If we are unable to establish or manage strategic collaborations in the future, our revenue and product development may be limited.**

Our strategy may include reliance on strategic collaborations for co-promotion of FavId in the United States. In addition, we expect to rely on strategic collaborators for commercialization of FavId outside of the United States and, to an even greater extent, for worldwide development and commercialization of product candidates and programs for chronic autoimmune diseases, such as multiple sclerosis. To date, we have not entered into any agreements with third parties for any of these services and do not plan to establish a collaboration for FavId in the United States until we have received results of the pivotal Phase 3 clinical trial.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms, or at all. For example, potential partners may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of any collaborative relationship we may establish in the future will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we enter into development or commercialization collaborations, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our product candidates. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our product candidates. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development related to the collaboration could be delayed or terminated. Also, our collaborators may pursue development or commercialization of other products, product candidates or alternative technologies in preference to our product candidates. Finally, our collaborators may terminate our relationships, and we may be unable to establish additional corporate collaborations in the future on acceptable terms, or at all.

**Our efforts to discover, develop and commercialize new product candidates beyond FavId are at an early stage and are subject to a high risk of failure.**

Our strategy is focused on the research, development and commercialization of targeted immunotherapies for the treatment of cancer and other diseases of the immune system. The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. We have only recently begun to direct significant effort toward the development of product candidates in addition to FavId, such as FAV-201 for T-cell lymphoma and a preclinical product candidate for the treatment of multiple sclerosis. We do not know whether our planned preclinical studies or clinical trials for these other product candidates will begin on time or be completed on schedule, or at all. In addition, we do not know whether these clinical trials will result in marketable products. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. We do not anticipate that any of our product candidates will reach the market for at least several years.

We may not identify, develop or commercialize any additional new product candidates from our proprietary active immunotherapy technology. Our ability to develop successfully any of these product candidates depends on our ability to demonstrate safety and efficacy in humans through extensive preclinical testing and clinical trials and to obtain regulatory approval from the FDA and other regulatory authorities. Development of our product candidates will also depend substantially upon the availability of funding for our research and development programs.

**If our competitors develop and market products that are more effective than our existing product candidates or others we may develop, or obtain marketing approval before we do, our commercial opportunity may be reduced or eliminated.**

The development and commercialization of new pharmaceutical products for the treatment of cancer and autoimmune diseases is competitive, and we will face competition from numerous sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have substantially greater financial and technical resources and development, production and marketing capabilities than we do. In addition, many of these companies have more experience than we do in preclinical testing, clinical trials and manufacturing of biologic therapeutics, as well as in obtaining FDA and foreign regulatory approvals. We will also compete with academic institutions, governmental agencies and private organizations that are conducting research in the fields of cancer and autoimmune disease. Competition among these entities to recruit and retain highly qualified scientific, technical and professional personnel and consultants is also intense.

We are aware of a number of companies that are developing active immunotherapies to treat B-cell NHL. Genitope Corporation is evaluating its idiotype immunotherapy product candidate in a Phase 3 clinical trial in patients with follicular B-cell NHL who are in remission following prior treatment with chemotherapy. Antigenics, Inc. completed a Phase 2 clinical trial evaluating its active immunotherapy candidate in indolent NHL patients. The NCI is also conducting a Phase 3 clinical trial of an active idiotype immunotherapy in collaboration with Accentia Biopharmaceuticals.

Several companies are engaged in the development and commercialization of passive immunotherapy products for the treatment of B-cell NHL that may compete with FavId. Genentech and Biogen Idec are co-marketing Rituxan for the treatment of relapsed or refractory, indolent B-cell NHL. Biogen Idec is also marketing Zevalin, its passive radioimmunotherapy product. GlaxoSmithKline plc currently markets Bexxar, a passive radioimmunotherapy product.

The most recent advances in the treatment of B-cell NHL have involved the combination of existing products and changes to approved schedules and doses, particularly for Rituxan. Numerous clinical trials reported in recent years have indicated that additional doses of Rituxan and maintenance dosing of Rituxan can improve TTP in patients who respond to therapy. Combination therapies involving chemotherapeutic or immunostimulatory drugs in combination with Rituxan at various

doses and schedules may provide patients with an increase in TTP over that expected with Rituxan alone. Accordingly, we may face competition as a result of developments in this area.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and obtain all requisite regulatory approvals in a cost-effective manner;
- reliably and cost-effectively manufacture sufficient quantities of our products;
- maintain a proprietary position for our manufacturing process and other technology;
- price our products competitively;
- obtain appropriate reimbursement approvals for our products;
- establish an adequate sales and marketing force for our products; and
- attract and retain key personnel.

In addition, our ability to compete effectively will depend on the relative efficacy and safety of other active immunotherapy products approved for sale as compared to our own products.

**We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.**

There have been a number of legislative and regulatory proposals aimed at changing the healthcare system and pharmaceutical industry, including reductions in the cost of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, the Prescription Drug and Medicare Improvement Act of 2003 was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

**We depend on attracting and retaining key scientific and management personnel to advance our technology, and the loss of these personnel could impair the development of our products.**

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly John P. Longenecker, Ph.D., our President and Chief Executive Officer, and Daniel P. Gold, Ph.D., one of our co-founders and our Chief Scientific Officer. The loss of services of Dr. Longenecker or Dr. Gold, or one or more of our other members of senior management, could delay or prevent the successful completion of our pivotal Phase 3 clinical trial or the commercialization of FavId. Although we have employment agreements with each of our executives, their employment with us is "at will," and each executive can terminate his or her agreement with us at any time. We do not carry "key person" insurance covering members of senior management, other than Drs. Longenecker and Gold. This insurance may not continue to be available on commercially reasonable terms and may prove inadequate to compensate us for the loss of their services.

The competition for qualified personnel in the biotechnology field is intense. In particular, our manufacturing process depends on our ability to attract and retain qualified manufacturing and quality control personnel. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. We are not aware of any key personnel planning to retire or terminate their employment in the near future.

**We will need to increase the size of our organization, and we may experience difficulties in managing growth.**

As of December 31, 2006, we had 151 employees. Of these, 123 employees were in research and development comprised of 88 in manufacturing, quality control and quality assurance, 32 in research and process development, and three members of senior management. Of the remaining employees, three were members of senior management and 25 were in marketing, general and administration. We will need to expand our financial, managerial, operational and other resources in order to continue our clinical trials and commercialize FavId, FAV-201, or any other product candidates that we may develop. Future growth would impose significant added responsibilities on our management team, including the need to identify, recruit, maintain and integrate additional employees. Our ability to commercialize FavId, FAV-201, or any other product candidates that we may develop, and our future financial performance in general, will depend in part on our ability to manage any future growth effectively. In order to meet these challenges, we would need to:

- manage our clinical trials effectively;
- manage our research and development efforts effectively;
- develop our administrative, accounting and management information systems and controls; and
- hire, train and integrate additional management, administrative, manufacturing and sales and marketing personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our business or future prospects.

**If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.**

Our research and development and manufacturing activities involve the use of biological and hazardous materials that could be dangerous to human health, safety or the environment. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources. We currently maintain property and casualty insurance coverage which covers liability for hazardous and controlled materials. However, this insurance coverage may not be sufficient to cover our liability and we may not be able to obtain sufficient coverage in the future at a reasonable cost. In addition, we may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, or OSHA, and the Environmental Protection Agency, or EPA, and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act. OSHA, the EPA or other agencies may adopt regulations that adversely affect our research and development programs.

**We face a risk of product liability claims and may not be able to obtain adequate insurance.**

Our business exposes us to potential liability risks that may arise from the clinical testing of our product candidates and the manufacture and sale of any approved products. These risks will exist even with respect to those product candidates that are approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA. Any product liability claim or series of claims brought against us could significantly harm our business by, among other things, reducing demand for our products, injuring our reputation and creating significant adverse media attention and costly litigation. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Any judgment against us that is in excess of our insurance policy limits would have to be paid from our cash reserves, which would reduce our capital resources. We currently maintain clinical trial insurance. Although we believe our current insurance coverage is adequate, we cannot be certain that it will be sufficient. Furthermore, we cannot be certain that our current insurance coverage will continue to be available, or that increased coverage, which will be necessary if we are able to commercialize our products, will be available in the future on reasonable terms, or at all. Further, we may not have sufficient capital resources to pay a judgment, in which case our creditors could levy claims against our assets, including our intellectual property.

**We could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state anti-referral laws.**

If we are able to commercialize FavId or any other product candidates that we may develop, we will be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. Because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices: could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations. In addition, some allegations under these laws have been claimed to violate the False Claims Act, discussed in more detail below.

In addition, if we are able to commercialize FavId or any other product candidates that we may develop, we could become subject to false claims litigation under federal statutes, which can lead to civil money penalties, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. These false claims statutes include the False Claims Act, which allows any person to bring suit on behalf of the federal government alleging the submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against biotechnology companies have increased significantly in recent years and have increased the risk that a healthcare company will have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. We cannot assure you that we will not become subject to such litigation or, if we are not successful in defending against such actions, that such actions will not have a material adverse effect on our business, financial condition and results of operations. In addition, we cannot assure you that the costs of defending claims or allegations under the False Claims Act will not have a material adverse effect on our business, financial condition and results of operations.

#### **Risks Related to Our Intellectual Property and Potential Litigation**

**If we are unable to obtain and maintain protection for our intellectual property, the value of our technology and products may be adversely affected.**

Our business and competitive positions are dependent upon our ability to protect our proprietary technology. Our success will depend in large part on our ability to obtain and maintain patent protection for our product and technologies, preserve trade secrets and operate without infringing the intellectual property right of others. Because of the substantial length of time and expense associated with development of new products, we, along with the rest of the biopharmaceutical industry, place considerable importance on obtaining and maintaining patent protection for new technologies, products and processes. The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including us, are generally uncertain and involve complex legal and factual questions. Our patent applications may not protect our technologies and products because, among other things:

- there is no guarantee that any of our pending patent applications will result in issued patents;
- we may develop additional proprietary technologies that are not patentable;
- there is no guarantee that any patents issued to us, our collaborators or our licensors will provide a basis for a commercially viable product;
- there is no guarantee that any patents issued to us or our collaborators or our licensors will provide us with any competitive advantage;
- there is no guarantee that any patents issued to us or our collaborators or our licensors will not be challenged, circumvented or invalidated by third parties; and

- there is no guarantee that any patents previously issued to others or issued in the future will not have an adverse effect on our ability to do business.

We attempt to protect our intellectual property position by filing United States patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently we own U.S. Patent No. 6,911,204 concerning the treatment of NHL with our technology together with four pending United States patent applications covering methods of treating immune system diseases, including B-cell and T-cell lymphomas, using our proprietary immunotherapy production methods, as well as methods for combining the idiotype immunotherapies with other therapies that are used to treat diseases of the immune system.

Outside of the United States, we have six issued patents and over twenty pending patent applications. Limitations on patent protection in some countries outside the United States, and the differences in what constitutes patentable subject matter in these countries, may limit the protection we have under patents issued to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the United States. In determining whether or not to seek a patent or to license any patent in a particular foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential of our product candidates in the jurisdiction, and the scope and enforceability of patent protection afforded by the law of the jurisdiction. Failure to obtain adequate patent protection for our proprietary product candidates and technology would impair our ability to be commercially competitive in these markets.

Although we believe our issued patents, as well as our patent applications if they issue as patents, will provide a competitive advantage, we may not be able to develop additional patentable products or processes. Further, we may not be able to obtain patents from any of the pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect our technology. In addition, any patents or patent rights we obtain may be circumvented, challenged or invalidated by our competitors.

**We are not able to prevent others, including potential competitors, from using certain types of patient-specific idiotype protein-KLH conjugates, like those we use in our lead product candidate, FavId, for the treatment of indolent B-cell NHL.**

Certain types of patient-specific idiotype-KLH conjugates, comprising single idiotype proteins, and their use for the treatment of indolent B-cell NHL are in the public domain and therefore cannot be patented. Consequently, we may only be able to seek patent protection for methods of treating immune system diseases, including B-cell and T-cell lymphomas, using our proprietary immunotherapy production methods for making idiotype protein conjugates and compositions comprising such conjugates, as well as methods for combining the idiotype or T-cell receptor-based immunotherapies with other therapies that are used to treat diseases of the immune system. As a result, we may not be able to prevent other companies using different manufacturing processes from developing active immunotherapies that directly compete with FavId.

**We may have to engage in costly litigation to enforce our proprietary rights or to defend challenges to our intellectual property by our competitors, which may harm our business, results of operations, financial condition and cash flow.**

The pharmaceutical field is characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our patents will be enforceable. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Litigation may be necessary to protect our patent position, and we cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our patent rights. In addition, our efforts to protect our patents may not be successful.

**Our ability to market our products may be impaired by the intellectual property rights of third parties.**

Our commercial success will depend in part on not infringing the patents or proprietary rights of third parties. We are aware of competing intellectual property relating to active idiotype immunotherapies for cancer. Competitors or third parties may be issued, or may currently hold, patents that may cover subject matter that we use in developing the technology required to bring our product candidates to market, that we use in producing our product candidates, or that we use in treating patients with our product candidates. In addition, from time to time we receive correspondence inviting us to license patents from third parties. While we currently believe we have freedom to operate in our area, others may challenge our position in the

future. There has been, and we believe that there will continue to be, significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

While we believe that our pre-commercialization activities fall within the scope of an available exemption against patent infringement provided by 35 U.S.C. §271(e), and that our subsequent manufacture of our commercial products will also not require the license of any patents, claims may be brought against us in the future based on these or other patents held by others. As our product candidates progress toward commercialization, competitors or other parties may assert that we infringe on their patents or proprietary rights.

In particular, we are aware of the following third party patents:

- Genentech and City of Hope National Medical Center hold patent rights related to the expression of recombinant antibodies;
- Genitope holds patent rights relating to immunotherapy using idiotype proteins produced using T-lymphoid cells for the treatment of B-Cell lymphoma; and
- Schering Corp. holds patent rights relating to the use of GM-CSF as a vaccine adjuvant for use against infectious diseases.

The first patent listed above was issued to Genentech in 2001. We do not believe that this patent covers our technology, and we note that in May 2005, a third party filed a request for reexamination of this patent with the U.S. Patent and Trademark Office, requesting that the claims of this patent be reexamined as to their patentability; the reexamination is currently pending. During reexamination the issued claims were rejected; proceedings before the U.S. Patent and Trademark Office continue. If this patent reissues and we decide to attempt to obtain a license for this patent, we cannot guarantee that we would be able to obtain such a license on commercially reasonable terms, or at all.

Additionally, because patent prosecution can proceed in secret prior to issuance of a patent, third parties may obtain other patents with claims of unknown scope relating to our product candidates, which they could attempt to assert against us. Further, as we develop our products, we may infringe the current patents of third parties or patents that may issue in the future. Third parties could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or products. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. However, there can be no assurance that any such license will be available on acceptable terms or at all. To enforce patents issued to us or to determine the scope and validity of other parties' proprietary rights, we may also become involved in litigation or in interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial costs to us, regardless of the outcome of the litigation, or an adverse decision as to the priority of our inventions. Ultimately, as a result of patent infringement claims, our business could be harmed and we could be prevented from commercializing a product, or forced to cease some aspect of our business operations.

**If we are not able to protect and control unpatented trade secrets, know-how and other technological innovation, we may suffer competitive harm.**

We also rely on trade secrets to protect our technology, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We attempt to protect our trade secrets by requiring each of our employees, consultants and advisors to execute a non-disclosure and assignment of invention agreement before beginning his or her employment, consulting or advisory relationship with us. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, or those of our future collaborators, may become known or may be independently discovered by others, which could adversely affect the competitive position of our product candidates.

## Risks Related to the Securities Markets and Ownership of Our Common Stock

Until our initial public offering in February 2005, there was no public market for our common stock, and the price of our common stock may be volatile and could decline significantly.

Until our initial public offering, or IPO, in February 2005, there was no public market for our common stock, and despite our IPO, an active public market for these shares may not be sustained. Our stock price has traded in the range of \$7.77- \$2.39 from the commencement of our IPO on February 2, 2005 to March 22, 2007.

The stock market in general has been experiencing dramatic fluctuations that have often been unrelated to the operating performance of companies. The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. If market-based or industry-based volatility continues, the trading price of our common stock could decline significantly, independent of our actual operating performance, and you could lose all or part of your investment. The market price of our common stock could fluctuate significantly as a result of several factors, including:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of FavId or any other product candidates that we may develop, or delays in the FDA review process;
- actions taken by regulatory agencies with respect to FavId and FAV-201, or any other product candidates that we may develop, or our clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States and foreign countries;
- success of our research efforts and clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

Specifically, you may not be able to resell your shares at or above the price you paid for such shares. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

**Concentration of ownership among our existing officers, directors and principal stockholders may prevent other stockholders from influencing significant corporate decisions and depress our stock price.**

As of December 31, 2006, our officers and directors and stockholders affiliated with our directors together beneficially held approximately 37.9% of our outstanding common stock on an as-converted basis. If some or all of these officers, directors and principal stockholders act together, they will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors, the merger, consolidation or sale

of all or substantially all of our assets, and any other significant corporate transaction. The interests of this concentration of ownership may not always coincide with our interests or the interests of our other stockholders. For instance, officers, directors and principal stockholders, acting together, could cause us to enter into transactions or agreements that we would not otherwise consider. Similarly, this concentration of ownership may have the effect of delaying or preventing a change in control of us otherwise favored by our other stockholders. This concentration of ownership also could depress our stock price.

**Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and applicable Delaware law may prevent or discourage third parties or our stockholders from attempting to replace our management or influencing significant decisions.**

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change in control of us or our management, even if doing so would be beneficial to our stockholders. These provisions include:

- dividing our board of directors into three classes serving staggered three-year terms;
- authorizing our board of directors to issue preferred stock without stockholder approval;
- prohibiting cumulative voting in the election of directors;
- prohibiting stockholder actions by written consent;
- limiting the persons who may call special meetings of stockholders;
- prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66.7% stockholder approval; and
- requiring advance notice for raising business matters or nominating directors at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our board of directors. Together, these charter and statutory provisions could make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

**Because we do not intend to pay any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless they sell them.**

We have never paid or declared any cash dividends on our capital stock and intend to retain any future earnings to finance the development and expansion of our business. The payment of dividends by us on our common stock is limited by our debt agreements. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Unless we pay dividends, our stockholders will not be able to receive a return on their shares unless they sell them.

**We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.**

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules related to corporate governance and other matters subsequently adopted by the SEC and the Nasdaq Stock Market, could result in increased costs to us. The new rules and any related regulations that may be proposed in the future could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

**Item 1B. *Unresolved Staff Comments***

Not applicable.

**Item 2. *Properties***

We lease approximately 128,000 square feet of space in two adjacent buildings in San Diego, California under two lease agreements. The lease term for the 80,000 square foot facility expires on June 30, 2025, but may be extended at our option for two additional five-year periods. The lease term on the adjacent 48,000 square foot facility expires June 30, 2025, but may be terminated, at no cost to us, as of June 1, 2017, upon six months' prior notice to the landlord. We plan to dedicate the existing 80,000 square feet of space for the commercial-scale manufacturing of FavId if it is approved and of product for additional clinical trials. The 48,000 square foot facility houses our corporate offices. Construction of improvements for the expansion of manufacturing capacity in the 80,000 square foot facility began in June 2006.

**Item 3. *Legal Proceedings***

We are currently not a party to any material legal proceeding. We may be subject to various claims and legal actions arising in the ordinary course of business from time to time.

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

No matters were submitted to us by a vote of the security holders during the quarter ended December 31, 2006.

## PART II

### Item 5. *Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

#### Common Stock Market Price

Our common stock commenced trading on the Nasdaq National Market on February 2, 2005 under the symbol "FVRL." Prior to such time, there was no public market for our common stock. The table below sets forth the high and low sales prices of common stock:

	<u>High</u>	<u>Low</u>
<b>2006</b>		
January 1, 2006 – March 31, 2006 .....	7.77	3.60
April 1, 2006 – June 30, 2006 .....	6.80	4.18
July 1, 2006 – September 30, 2006 .....	4.90	3.92
October 1, 2006 – December 31, 2006.....	5.25	2.39
<b>2005</b>		
February 2, 2005 – March 31, 2005 .....	7.50	4.79
April 1, 2005 – June 30, 2005 .....	5.24	3.46
July 1, 2005 – September 30, 2005 .....	6.60	3.83
October 1, 2005 – December 31, 2005.....	4.72	3.20

As of March 22, 2007 we had outstanding 32,503,721 shares of common stock held by approximately 1,686 stockholders including beneficial owners of the common stock whose shares are held in the names of various dealers, clearing agencies, banks brokers and other fiduciaries.

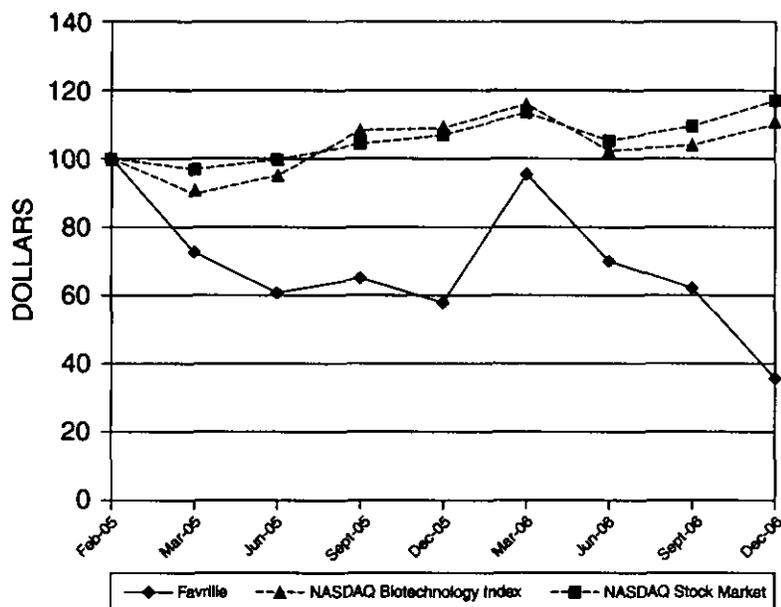
#### Performance Measurement Comparison

*The material in this section is not "soliciting material," is not deemed "filed" with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Favrilite under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.*

The following graph shows a comparison of the total cumulative returns of an investment of \$100 in cash (i) on February 3, 2005, the first trading day following our initial public offering, in our common stock, (ii) on January 31, 2005 in the Nasdaq Composite Index, U.S. Companies and (iii) on January 31, 2005 in the Nasdaq Biotechnology Index, in each case through December 31, 2006. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock. The graph assumes that all dividends have been reinvested (to date, we have not declared any dividends).

## COMPARISON OF 23-MONTH TOTAL RETURN

AMONG FAVRILLE, INC.,  
THE NASDAQ STOCK MARKET (U.S.) INDEX,  
AND THE NASDAQ BIOTECHNOLOGY INDEX



### Dividends

We have never declared or paid any cash dividends on our capital stock. The payment of dividends by us on our common stock is limited by our debt agreements. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

### Use of Proceeds from the Sale of Registered Securities

Our initial public offering of our common stock, par value \$0.001, was effected through a Registration Statement on Form S-1 (File No. 333-114299) that was declared effective by the Securities and Exchange Commission on February 2, 2005. On February 7, 2005, 6 million shares of our common stock were sold for an aggregate offering price of \$42.0 million. On March 7, 2005, 285,000 shares of our common stock were sold for an aggregate offering price of \$2.0 million upon the partial exercise of the underwriters' over-allotment option. Our initial public offering resulted in aggregate proceeds to us of approximately \$39.5 million, net of underwriting discounts and commissions of approximately \$3.1 million and offering expenses of approximately \$1.4 million, through a syndicate of underwriters managed by Bear, Stearns & Co. Inc., CIBC World Markets Corp., Needham & Company, Inc. and A.G. Edwards & Sons, Inc.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or person owning ten percent or more of any class of our equity securities or to any other affiliates. All offering expenses were paid directly to others.

We had invested \$40.9 million in proceeds from the offering, net of underwriting discounts and commissions but before expenses, in government agency securities, corporate bonds and notes and money market funds. Through December 31, 2006, we used all of the proceeds from our initial public offering to develop and prepare for filing a biologic license application, or BLA, for regulatory approval of FavId, for development of our other product candidates, for general and administrative expenses, and for working capital, including debt repayments.

The foregoing payments were direct payments made to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of any class of our equity securities or any other affiliate, except that the

proceeds used for salaries expense included regular compensation for our officers and directors. The use of proceeds does not represent a material change from the use of proceeds described in the prospectus we filed pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended, with the Securities and Exchange Commission on February 3, 2005.

### Issuer Purchase Of Equity Securities

On October 16, 2006, we repurchased 254 restricted shares of common stock from an employee whose employment had terminated. These restricted common stock shares had been issued upon the early exercise of employee options and upon termination had not yet vested.

### Item 6. Selected Financial Data

The following selected financial data set forth below should be read in conjunction with Financial Statements and Notes thereto included in Item 8 and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7. The selected financial data for the years ended December 31, 2006, 2005 and 2004 and the selected balance sheet data as of December 31, 2006 and 2005 are derived from our audited financial statements, which are included in Item 8. The selected financial data for the years ended 2003 and 2002 and the selected balance sheet data as of December 31, 2004, 2003 and 2002 are derived from our audited financial statements, which are not included in this report. Our historical results are not necessarily indicative of our future results.

	Years ended December 31,				
	2006	2005	2004	2003	2002
Operating expenses:					
Research and development .....	\$ 31,050	\$ 29,592	\$ 19,890	\$ 10,606	\$ 5,308
General and administrative .....	11,170	6,776	5,716	2,433	2,017
Total operating expenses .....	<u>42,220</u>	<u>36,368</u>	<u>25,606</u>	<u>13,039</u>	<u>7,325</u>
Loss from operations .....	(42,220)	(36,368)	(25,606)	(13,039)	(7,325)
Interest income .....	2,648	1,492	375	108	167
Interest expense .....	(834)	(703)	(817)	(332)	(88)
Other income (expense) .....	(105)	(6)	12	8	—
Loss on extinguishment of debt .....	—	(290)	—	—	—
Total other income (expense), net .....	<u>1,709</u>	<u>493</u>	<u>(430)</u>	<u>(216)</u>	<u>79</u>
Net loss .....	(40,511)	(35,875)	(26,036)	(13,255)	(7,246)
Deemed dividend—beneficial conversion feature for Series C redeemable convertible preferred stock .....	—	—	(28,103)	—	—
Accretion of Series C redeemable convertible preferred stock issuance costs .....	—	(6)	(51)	—	—
Net loss applicable to common stockholders .....	<u>\$ (40,511)</u>	<u>\$ (35,881)</u>	<u>\$ (54,190)</u>	<u>\$ (13,255)</u>	<u>\$ (7,246)</u>
Historical net loss per share:					
Basic and diluted .....	<u>\$ (1.49)</u>	<u>\$ (1.99)</u>	<u>\$ (51.48)</u>	<u>\$ (16.97)</u>	<u>\$ (11.87)</u>
Weighted-average shares—basic and diluted .....	<u>27,247,385</u>	<u>18,060,992</u>	<u>1,052,624</u>	<u>781,054</u>	<u>610,709</u>

	As of December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents .....	\$ 14,249	\$ 12,065	\$ 25,065	\$ 5,610	\$ 10,030
Short-term investments .....	28,160	22,427	1,493	—	—
Working capital .....	31,504	28,986	22,176	3,466	9,226
Total assets .....	72,289	47,007	39,130	14,932	11,998
Debt (less current portion) .....	5,754	3,532	4,224	3,501	207
Redeemable convertible preferred stock .....	—	—	43,672	—	—
Deficit accumulated during the development stage .....	(155,894)	(115,383)	(79,502)	(25,312)	(12,057)
Total stockholders' equity (deficit).....	44,635	35,714	(14,654)	8,278	10,727

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

*You should read the following discussion and analysis together with our financial statements and accompanying notes included elsewhere in this report. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of several factors, including those set forth under Item 1A of Part I and elsewhere in this Report, our actual results and the timing of selected events may differ materially from those anticipated in these forward-looking statements.*

##### Overview

We are a biopharmaceutical company focused on the development and commercialization of targeted immunotherapies for the treatment of cancer and other diseases of the immune system. We have developed a proprietary technology that enables us to manufacture active immunotherapy products that are designed to stimulate a patient's immune system to mount a specific and sustained response to disease. Our lead product candidate, FavId, is an active immunotherapy for the treatment of B-cell non-Hodgkin's lymphoma, or NHL. We initiated a pivotal Phase 3 clinical trial of FavId in patients with follicular B-cell NHL in July 2004 and completed patient enrollment in January 2006 with 349 patients randomized into the trial. In addition, FavId has been evaluated in several multi-center, open-label Phase 2 clinical trials involving more than 130 patients.

We believe FavId may be effective in treating other types of B-cell NHL. Four additional Phase 2 clinical trials of FavId are ongoing. One of these clinical trials is being conducted under a separate physician-sponsored Investigational New Drug, or IND, application in the United States. Moreover, we believe our active immunotherapy expertise and proprietary manufacturing technology may enable us to develop additional product candidates for other oncology indications, such as T-cell lymphoma, and for autoimmune diseases. In June 2006, we received an allowance from the FDA for an IND for our second product candidate, FAV-201, for the treatment of cutaneous T-cell lymphoma. We have retained exclusive worldwide commercialization rights to all of our product candidates.

We were incorporated in Delaware in January 2000. As of December 31, 2006, we had not generated any revenues, and we had financed our operations and internal growth through private placements of our stock and warrants, equipment and leasehold debt financings and the sale of common stock in our initial public offering, or IPO, in February 2005. We are a development stage company and have incurred significant losses since our inception in 2000, as we have devoted substantially all of our efforts to research and development activities, including clinical trials. As of December 31, 2006, our deficit accumulated during the development stage was approximately \$155.9 million. We expect to incur substantial and increasing losses for the next several years as we:

- continue to develop and prepare for the commercialization of our lead product candidate, FavId;
- expand our research and development programs;
- expand our current manufacturing capabilities to support commercial manufacturing of FavId; and
- acquire or in-license oncology products that are complementary to our own.

## Financial Operations Overview

**Research and Development Expense.** Research and development expense consists primarily of costs associated with clinical trials of our product candidates, including the costs of manufacturing our product candidates, compensation and other expenses related to research and development personnel, facilities costs and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of FavId. We have completed enrollment in two Phase 2 clinical trials and continue to evaluate the results. We initiated our pivotal Phase 3 clinical trial of FavId following Rituxan in patients with follicular B-cell NHL in July 2004 and completed patient enrollment in the trial in January 2006. In addition, four additional Phase 2 clinical trials of FavId are ongoing.

From inception through December 31, 2006, we incurred costs of approximately \$99.9 million associated with the research and development of FavId, which represents substantially all of our research and development costs to date. We expect our research and development costs to increase as we advance FavId and new product candidates into later stages of clinical development. While difficult to predict, we estimate that research and development costs required to complete the development of and file a Biologics Licensing Application, or BLA, for FavId will be an additional \$55 million. We are unable to estimate with any certainty the costs we will incur in the continued development of other product candidates for commercialization. On an ongoing basis, we expect to expand our research and development activities to include clinical development of FAV-201 and preclinical research of treatments for autoimmune diseases, initially multiple sclerosis.

Clinical development timelines, likelihood of success and total costs vary widely. Although we are currently focused primarily on FavId, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct toward each project on an ongoing basis in response to the scientific and clinical success of each product candidate.

At this time, due to the risks inherent in the clinical trial process, clinical trial completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for our product candidates could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when, if ever, any cash flows from our current product candidates will commence.

**Marketing, General and Administrative Expense.** Marketing, general and administrative expenses consist primarily of compensation and other expenses related to our marketing and corporate administrative employees, legal fees and other professional services expenses. We anticipate increases in marketing, general and administrative expenses as we add personnel and continue to develop and prepare for commercialization of our product candidates.

**Interest Income.** Interest income primarily consists of interest earned on our cash reserves, cash invested in money market funds, government securities, corporate notes and bonds and certificates of deposit.

**Interest Expense.** Interest expense represents interest on our debt, including capital leases.

## Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. While our significant accounting policies are described in more detail in Note 1 of the Notes to Financial Statements included elsewhere in this report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements:

**Stock-Based Compensation.** Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," (SFAS 123(R)). Under SFAS 123(R), stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We adopted the provisions of SFAS 123(R) using a modified prospective application. Accordingly, prior periods have not been revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date, which are subsequently modified or cancelled. Estimated compensation

expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS 123, *Accounting for Stock-Based Compensation*. We utilize the Black-Scholes valuation model for estimating the fair value of the stock-based compensation granted both before and after the adoption of SFAS 123(R). The Black-Scholes valuation model requires extensive use of accounting judgment and financial estimates, including estimates of the expected term participants will retain their vested stock options before exercising them, the estimated volatility of our common stock price over the expected term and the number of options that will be forfeited prior to the completion of their vesting requirements. Application of alternative assumptions could produce significantly different estimates of the fair value of stock-based compensation and consequently, the related amount of stock-based compensation expense recognized in the Statement of Operations could have been significantly different than the amounts recorded. Under provisions of SFAS 123(R), we recorded approximately \$4.0 million of stock-based compensation expense in our Statement of Operations for the year ended December 31, 2006. Prior to the adoption of SFAS 123(R), we recorded approximately \$2.9 million and \$2.4 million of stock-based compensation expense for certain options granted during 2005 and 2004 in our Statement of Operations for the years ended December 31, 2005 and 2004, respectively, under the provisions of APB 25 based upon their intrinsic value. At December 31, 2006, the total compensation cost related to unvested stock-based awards granted to employees under our stock award plans but not yet recognized was approximately \$6.7 million, net of estimated forfeitures of approximately \$380,000. This cost will be amortized on a straight-line basis over a weighted-average period of approximately 1.25 years and will be adjusted for subsequent changes in estimated forfeitures. See Note 5 to the Financial Statements for further information on our accounting for stock-based compensation.

**Lease Obligation.** We recognize rent expense on a straight-line basis over the reasonably assured lease term. Our lease agreements provide for scheduled rent increases during the lease terms or for rental payments commencing at a date other than the date of initial occupancy. We include any rent escalations and other rent holidays in our straight-line rent expense. In addition, tenant improvements paid by the landlord are capitalized as leasehold improvements and amortized over the shorter of their estimated useful lives or the remaining lease term, while the tenant improvement allowance is recorded as deferred rent and recovered ratably over the remaining term of the lease.

**Capitalized Software.** Software developed for internal use, whether purchased or developed, is capitalized and amortized using the straight-line method over an estimated useful life of five years. Costs incurred until the point the project has reached development stage are expensed in accordance with Statement of Position ("SOP") 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use.* Determining when a project has reached the development stage, requires the use of judgment. Subsequent additions, modifications or upgrades to internal-use software are capitalized only to the extent that they allow the software to perform a task it previously did not perform. Software maintenance and training costs are expensed in the period in which they are incurred.

Management has discussed the development and selection of these critical accounting policies with the Audit Committee of our Board of Directors and the Audit Committee has reviewed the disclosures presented above relating to them.

## **Results of Operations**

### ***Comparison of Fiscal Years Ended December 31, 2006 to 2005***

**Research and Development.** Research and development expense increased from approximately \$29.6 million in 2005 to \$31.1 million in 2006. The increase of \$1.5 million, or 5%, was due primarily to an increase of approximately \$2.4 million for the compensation costs of additional personnel and the 2006 merit bonus program; an increase of approximately \$950,000 primarily due to the increased amortization of deferred rent associated with the amended long-term lease agreements related to our facility expansion; an increase of approximately \$650,000 to support our pivotal Phase 3 clinical trial and Information Technology outside services, clinical and regulatory third-party consulting services to prepare for the commercialization of FavId; and an increase of approximately \$550,000 in stock-based compensation costs due to the implementation of SFAS 123(R); offset by a decrease of approximately \$2.3 million of raw materials and supplies for the manufacture of FavId due to the completion of patient enrollment into our pivotal Phase 3 clinical trial in the first quarter of 2006 and a decrease of approximately \$1.3 million in clinical trial site costs.

**Marketing, General and Administrative.** Marketing, general and administrative expense increased from approximately \$6.8 million in 2005 to \$11.2 million in 2006. The increase of \$4.4 million, or 65%, primarily reflects an increase of approximately \$1.9 million in personnel and outside services related to strategic marketing programs; an increase of approximately \$800,000 in compensation costs associated with additional administrative personnel, discretionary bonuses paid in 2006 and the 2006 merit bonus program; an increase of approximately \$600,000 in stock-based compensation due to

the implementation of SFAS 123(R); and an increase of approximately \$550,000 in legal and audit fees and other public company expenses.

*Interest Income.* Interest income increased from approximately \$1.5 million in 2005 to \$2.6 million in 2006. The increase of \$1.1 million, or 73%, was primarily a result of rising interest rates during 2006 and the higher average cash, cash equivalents and short term investments balance of \$51.7 million available for investment during 2006 as compared to \$46.0 million in 2005. The higher cash, cash equivalents and short term investments is due to the addition of net proceeds of \$45 million from our private placement of common stock and warrants in March 2006.

#### ***Comparison of Fiscal Years Ended December 31, 2005 to 2004***

*Research and Development.* Research and development expense increased from approximately \$18.7 million in 2004 to \$28.2 million in 2005. The increase of \$9.5 million, or 51%, was primarily due to an increase of approximately \$2.7 million in clinical trial site costs; an increase of \$2.6 million associated with an increase in personnel from 92 employees to 115 employees to support our Phase 3 clinical trial initiated in July 2004; an increase of \$2.2 million associated with supplies to support continued process and formulation development and the purchase of raw materials and supplies for our manufacture of FavId for our Phase 3 clinical trial, an increase of \$1.0 million paid to third party vendors providing support services for our Phase 3 clinical trial, including randomization of patients, radiology and laboratory management; and an increase of \$500,000 related to the operation of our manufacturing facility to support the production of FavId.

*General and Administrative.* General and administrative expense increased from approximately \$4.5 million in 2004 to \$5.3 million in 2005. The increase of \$800,000, or 18%, was primarily due to an increase of approximately \$620,000 associated with an increase in personnel from 17 employees to 21 employees; an increase of approximately \$640,000 in directors and officers liability insurance premiums and public company-related expenses incurred subsequent to our IPO; an increase of approximately \$180,000 in recruiting and relocation expenses related to the increase in personnel; an increase of approximately \$157,000 in fees related to market research studies, all of which were partially offset by a decrease of approximately \$790,000 due to non-recurring IPO related expenditures in 2004.

*Amortization of Stock-Based Compensation.* In connection with the grant of stock options, we recorded deferred stock-based compensation of \$350,000 and \$9.4 million in 2005 and 2004, respectively. Deferred stock-based compensation was reduced by amounts representing stock option cancellations and our repurchases of unvested restricted stock of approximately \$221,000 and \$224,000 in 2005 and 2004, respectively. We recorded these amounts as components of stockholders' equity and are amortizing the amounts, on a straight-line basis, as a non-cash charge to operations over the vesting period of the options. We recorded amortization of stock-based compensation of \$2.9 million and \$2.4 million in 2005 and 2004, respectively.

*Interest Expense.* Interest expense decreased from approximately \$817,000 in 2004 to \$703,000 in 2005. The decrease of \$114,000, or 14%, was primarily due to repayments of approximately \$5.5 million associated with our debt agreements with GE Technology Finance with interest rates ranging from 11.44% to 14.66%, offset by approximately \$5.0 million of new borrowings under new debt agreements, with Oxford Finance Corporation ("Oxford") and GE Capital Corporation with interest rates ranging from 9.34% to 12.17%.

*Interest Income.* Interest income increased from approximately \$375,000 in 2004 to \$1.5 million in 2005. The increase of \$1.1 million, or 300%, was primarily a result of the increase in interest rates during 2005 and the higher average cash, cash equivalents and short term investments balance of \$46.0 million available for investment during 2005 as compared to \$28.9 million in 2004. The higher cash, cash equivalents and short term investments is due to the addition of net proceeds of \$39.5 million from our IPO in February 2005.

#### **Liquidity and Capital Resources**

##### ***Sources of Liquidity***

We have historically funded our operations primarily through the sale of our equity securities and equipment and leasehold debt financing. As of December 31, 2006, we had received proceeds of approximately \$76.1 million, net of stock issuance costs from the sale of preferred stock which was converted to common stock; proceeds from the sale of common stock in our IPO of approximately \$39.5 million, net of underwriters' discounts and commissions and offering expenses; and proceeds of

approximately \$45.0 million from the sale of common stock and warrants to purchase common stock to certain investors, in a private placement, net of offering expenses.

As of December 31, 2006 we had financed the purchase of equipment and leasehold improvements through debt totaling approximately \$20.0 million. Total debt of \$10.7 million was outstanding at that date. These obligations are secured by our existing and future assets excluding intellectual property and are due in monthly installments through July 2010. They bear interest at stated rates ranging from approximately 9.34% to 12.17%. The debt agreements subject us to certain financial and non-financial covenants. As of December 31, 2006, we were in compliance with the terms of the debt agreements.

### ***Cash Flows***

As of December 31, 2006, cash, cash equivalents and short-term investments were approximately \$42.4 million as compared to \$34.5 million at December 31, 2005, an increase of approximately \$7.9 million. The increase resulted primarily from the \$45.0 million in net proceeds received from our private placement during the first quarter of 2006, partially offset by net cash used to fund ongoing operations.

Net cash used in operating activities was approximately \$32.1 million for the year ended December 31, 2006, compared to approximately \$29.6 million for the same period in 2005. The increase of approximately \$2.5 million is primarily due to an increase in operating expenses related to additional personnel and other expenses related to the continuing clinical development and preparation for commercialization of FavId.

Net cash used in investing activities for the year ended December 31, 2006 was approximately \$15.5 million compared to net cash used in investing activities of \$22.7 million for the same period in 2005. The decrease of approximately \$7.2 million is due to an increase of approximately \$16.0 million in short-term investment maturities net of short-term investment purchases, offset by an increase of approximately \$6.8 in property and equipment purchases and the increase of \$1.9 million in restricted cash to collateralize the letter of credit, which has been increased to \$3.5 million as required by our facility lease agreement.

Net cash provided by financing activities for the year ended December 31, 2006 totaled \$49.8 million, reflecting primarily the net proceeds from our private placement of common stock and warrants in the first quarter of 2006 of approximately \$45.0 million. Net cash provided by financing for the same period in 2005 totaled approximately \$39.4 million, reflecting primarily the net proceeds of our IPO of \$39.5 million in February 2005.

### ***Funding Requirements***

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

- the results of our ongoing pivotal Phase 3 clinical trial of FavId;
- magnitude and cost of our product development efforts and other research and development activities;
- rate of progress toward obtaining regulatory approval for our product candidates;
- costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- our ability to establish and maintain collaborative, licensing or other arrangements for the development, sale, marketing or distribution of our product candidates and the terms of those arrangements;
- effects of competing technological and market developments; and
- the success of the commercialization of FavId.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities and from equipment and leasehold improvement debt financing. In addition, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in obtaining

collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash, cash equivalents and short-term investments will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing may also adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of December 31, 2006, 2005 and 2004, we have not invested in any variable interest entities. We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties other than what is disclosed in Note 8 of the Notes to Financial Statements included elsewhere in this report.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Contractual Obligations**

The following summarizes our long-term contractual obligations as of December 31, 2006:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Payments Due by Period</u>			
		<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>4 to 5 Years</u>	<u>More than 5 Years</u>
			(in thousands)		
Long-term debt obligations(1).....	\$ 12,389	\$ 5,994	\$ 6,098	\$ 297	\$ —
Operating lease obligations.....	96,873	3,693	8,892	9,599	74,689
<b>Total.....</b>	<b>\$109,262</b>	<b>9,687</b>	<b>14,990</b>	<b>9,896</b>	<b>74,689</b>

(1) Includes monthly principal and interest payments. The stated annual rates of interest on the loans range from 9.34% to 12.17%.

Under terms of an existing supply agreement, we are obligated to pay fees of up to \$250,000 based upon certain events occurring. As the timing of those events is unknown they have been excluded from the table.

We also enter into agreements with service providers and clinical sites that administer and conduct our clinical trials, respectively. We make payments to the service providers and sites based upon the number of patients enrolled. For the years ended December 31, 2006, 2005 and 2004, we had made aggregate payments of \$5.2 million, \$5.1 million and \$2.1 million, respectively, in connection with our clinical trials. At this time, due to the variability associated with these agreements, we are unable to estimate with certainty the future patient enrollment costs we will incur and therefore have excluded these costs from the above table.

Purchase orders or contracts for the purchase of raw materials and other goods and services are not included in the table above. We are not able to determine the aggregate amount of such purchase orders that represents contractual obligations, as purchase orders may represent authorizations to purchase rather than binding agreements. Our purchase orders are based on our current manufacturing needs and are fulfilled by our vendors within relatively short time horizons.

As of December 31, 2006, we had \$3.5 million in restricted cash associated with our facility lease.

## **Related Party Transactions**

For a description of our related party transactions, see "Certain Relationships and Related Transactions."

## **Subsequent Event**

On February 12, 2007, we entered into common stock purchase agreements with certain investors relating to a registered direct offering of an aggregate 3,333,334 shares of our common stock at \$3.00 per share to the investors for gross proceeds of approximately \$10 million.

The common stock was issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 13, 2007, in connection with a shelf takedown from our Registration Statement on Form S-3 (File No. 333-135169) which became effective on July 11, 2006.

## **Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and will first be effective for us for the year beginning January 1, 2008. We are in the process of analyzing the effects of this pronouncement.

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 will be effective for fiscal years beginning after December 15, 2006 and will first be effective for us for the year beginning January 1, 2007. We are currently evaluating the impact of FIN 48 on results of operations, financial position and cash flows.

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

The primary objective of our investment activities is to preserve principal while maximizing income without significantly increasing risk. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the market value of the investment to fluctuate. To minimize this risk, we may maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and direct or guaranteed obligations of the United States government. The risk associated with fluctuating interest rates is limited to our investment portfolio and we do not believe that a 1% change in interest rates would have a significant impact on our interest income. As of December 31, 2006, all of our short-term investments were government agency securities, corporate notes and bonds, and our cash equivalents were held in checking accounts and money market funds.

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

The information required by this Item is included in Part IV, Item 15(a).

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

None.

### **Item 9A. *Controls and Procedures***

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 of the Securities Exchange Act of 1934, as amended, or Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to cause material information required to be disclosed by us in the reports that we file or submit under the Exchange Act to be recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

We believe that a control system, no matter how well designed and operated, is based in part upon certain assumptions about the likelihood of future events, and, therefore, can only provide reasonable, not absolute, assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company will be detected.

During the year ended December 31, 2006, there were no changes in our internal control over financial reporting which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information***

None.

## PART III

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

#### **Directors and Executive Officers**

See the section entitled "Executive Officers and Directors of the Registrant" in Part I, Item 1 hereof for certain information regarding executive officers and directors.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

The information required by this item with respect to Section 16(a) beneficial ownership reporting compliance is incorporated by reference from our Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, in connection with Favril's 2007 Annual Meeting of Stockholders (the "Proxy Statement").

#### **Code of Ethics**

We have adopted the Favril, Inc. Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at [www.favril.com](http://www.favril.com). If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

#### **Corporate Governance**

The information required by this item with respect to corporate governance matters is incorporated by reference from the Proxy Statement.

### **Item 11. *Executive Compensation***

The information required by this item is incorporated by reference from the Proxy Statement.

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

The following table sets forth certain information with respect to all of our equity compensation plans in effect as of December 31, 2006:

**Equity Compensation Plan Information**

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u> (a)	<u>Weighted-average exercise price of outstanding options, warrants and rights</u> (b)	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u> (c)
Equity compensation plans approved by security holders.....	2,365,384	\$ 3.99	631,508
Equity compensation plans not approved by security holders.....	—	—	—
<b>Total.....</b>	<b><u>2,365,384</u></b>	<b>---</b>	<b><u>631,508</u></b>

The other information required by this item is incorporated by reference from the Proxy Statement.

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

The information required by this item is incorporated by reference from the Proxy Statement.

**Item 14. Principal Accountant Fees and Services**

The information required by this item is incorporated by reference from the Proxy Statement.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

(1) Financial Statements

The following Financial Statements of Faville, Inc. are included in this Annual Report on Form 10-K beginning on page 52:

Report of Independent Registered Public Accounting Firm .....	57
Balance Sheets as of December 31, 2006 and 2005.....	58
Statements of Operations for each of the three years in the period ended December 31, 2006 and the period from January 21, 2000 (inception) to December 31, 2006 .....	59
Statements of Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2006 and the period from January 21, 2000 (inception) to December 31, 2006.....	60
Statements of Cash Flows for each of the three years in the period ended December 31, 2006 and the period from January 21, 2000 (inception) to December 31, 2006 .....	66
Notes to Financial Statements.....	68

(2) Financial Statement Schedules

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

(3) Exhibits

The exhibits required by Item 15(b) hereof are filed with, or incorporated by reference into, this Annual Report on Form 10-K.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Favrille, Inc.

We have audited the accompanying balance sheets of Favrille, Inc. (a development stage company) (the Company) as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006 and the period from January 21, 2000 (inception) to December 31, 2006. 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 the standards of the Public Company Accounting Oversight Board (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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Favrille, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, and the period from January 21, 2000 (inception) to December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, Favrille, Inc. changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards 123 (Revised 2004) on January 1, 2006.

/s/ Ernst & Young LLP

San Diego, California  
March 23, 2007

**FAVRILLE, INC.**  
(a development stage company)

**BALANCE SHEETS**  
(in thousands, except share and per share data)

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b> .....		
Current assets:		
Cash and cash equivalents .....	\$ 14,249	\$ 12,065
Short-term investments .....	28,160	22,427
Other current assets.....	850	935
Total current assets .....	43,259	35,427
Property and equipment, net .....	25,071	9,430
Restricted cash .....	3,451	1,550
Other assets.....	508	600
Total assets .....	\$ 72,289	\$ 47,007
<b>Liabilities and stockholders' equity</b> .....		
Current liabilities:		
Accounts payable and accrued liabilities .....	\$ 6,779	\$ 3,888
Current portion of debt .....	4,976	2,553
Total current liabilities.....	11,755	6,441
Debt, less current portion.....	5,754	3,532
Deferred rent.....	10,145	1,320
Commitments and contingencies .....		
Stockholders' equity:		
Preferred stock, \$0.001 par value 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2006 and 2005, respectively .....	—	—
Common stock, \$0.001 par value 75,000,000 shares authorized; 29,060,081 and 20,329,046 issued and outstanding at December 31, 2006 and 2005, respectively .....	29	20
Additional paid-in capital .....	200,497	156,882
Deferred stock-based compensation .....	—	(5,655)
Note receivable from stockholder .....	—	(96)
Accumulated other comprehensive income (loss) .....	3	(54)
Deficit accumulated during the development stage .....	(155,894)	(115,383)
Total stockholders' equity .....	44,635	35,714
Total liabilities and stockholders' equity .....	\$ 72,289	\$ 47,007

See accompanying notes.

**FAVRILLE, INC.**  
(a development stage company)

**STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	<u>Years ended December 31,</u>			<u>Period from</u>
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>January 21,</u> <u>2000</u> <u>(inception) to</u> <u>December 31,</u> <u>2006</u>
Operating expenses:				
Research and development .....	\$ 31,050	\$ 29,592	\$ 19,890	\$ 99,906
Marketing, general and administrative.....	<u>11,170</u>	<u>6,776</u>	<u>5,716</u>	<u>29,663</u>
Total operating expenses .....	42,220	36,368	25,606	129,569
Interest income.....	2,648	1,492	375	5,057
Interest expense .....	(834)	(703)	(817)	(2,841)
Other income (expense).....	(105)	(6)	12	(91)
Loss on extinguishment of debt.....	<u>—</u>	<u>(290)</u>	<u>—</u>	<u>(290)</u>
Total other income (expense), net.....	1,709	493	(430)	1,835
Net loss .....	<u>(40,511)</u>	<u>(35,875)</u>	<u>(26,036)</u>	<u>(127,734)</u>
Deemed dividend—beneficial conversion feature for Series C redeemable convertible preferred stock .....	—	—	(28,103)	(28,103)
Accretion of Series C redeemable convertible preferred stock issuance costs.....	<u>—</u>	<u>(6)</u>	<u>(51)</u>	<u>(57)</u>
Net loss applicable to common stockholders.....	<u>\$ (40,511)</u>	<u>\$ (35,881)</u>	<u>\$ (54,190)</u>	<u>\$ (155,894)</u>
Historical net loss per share:				
Basic and diluted.....	<u>\$ (1.49)</u>	<u>\$ (1.99)</u>	<u>\$ (51.48)</u>	
Weighted-average shares—basic and diluted .....	<u>27,247,385</u>	<u>18,060,992</u>	<u>1,052,624</u>	

See accompanying notes

**FAVRILLE, INC.**  
(a development stage company)  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
Period from January 21, 2000, (inception) to December 31, 2006  
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Issuance of common stock for cash	—	\$ —	588,713	\$ 1	\$ 2
Issuance of Series A Convertible Preferred Stock, in May and June, net of issuance costs of \$89,000	1,156,610	1	—	—	5,910
Net loss and comprehensive loss ...	—	—	—	—	—
Balance at December 31, 2000 .....	1,156,610	1	588,713	1	5,912
Issuance of common stock for cash	—	—	50,119	—	26
Exercise of options to purchase common stock .....	—	—	39,128	—	20
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	22
Repurchase of common stock .....	—	—	(2,120)	—	—
Net loss and comprehensive loss ...	—	—	—	—	—
Balance at December 31, 2001 .....	1,156,610	1	675,840	1	5,980
Issuance of common stock for cash	—	—	28,912	—	17
Issuance of Series B Convertible Preferred Stock net of issuance costs of \$136,000 .....	2,563,605	3	—	—	16,085
Conversion of Promissory Notes into Series B stock .....	103,123	—	—	—	653
Non-cash stock compensation .....	—	—	—	—	18
Issuance of common stock for license agreement .....	—	—	40,867	—	21
Issuance of options related to consulting agreement .....	—	—	—	—	1
Exercise of options to purchase common stock .....	—	—	196,474	—	102
Repurchase of common stock at ...	—	—	(3,919)	—	(2)
Net loss and comprehensive loss ...	—	—	—	—	—
Balance at December 31, 2002 .....	3,823,338	4	938,174	1	22,875
Issuance of Series B-2 Convertible Preferred Stock .....	1,681,992	2	—	—	10,522
Issuance of common stock for license agreement .....	—	—	38,553	—	24
Issuance of options related to consulting agreement .....	—	—	—	—	16
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	84
Exercise of options to purchase common stock .....	—	—	6,056	—	4
Repurchase of common stock .....	—	—	(1,687)	—	(1)
Deferred stock-based compensation related to issuance of stock options to employees .....	—	—	—	—	1,595
Amortization of stock-based compensation .....	—	—	—	—	—
Net loss and comprehensive loss ...	—	—	—	—	—
Balance at December 31, 2003 .....	5,505,330	6	981,096	1	35,119

	Deferred Stock-Based Compensation	Note Receivable from Stockholder	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Issuance of common stock for cash	\$ —	\$ —	\$ —	\$ —	\$ 3
Issuance of Series A Convertible Preferred Stock, in May and June, net of issuance costs of \$89,000	—	—	—	—	5,911
Net loss and comprehensive loss ...	—	—	—	(1,053)	(1,053)
Balance at December 31, 2000 .....	—	—	—	(1,053)	4,861
Issuance of common stock for cash	—	—	—	—	26
Exercise of options to purchase common stock .....	—	—	—	—	20
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	22
Repurchase of common stock .....	—	—	—	—	—
Net loss and comprehensive loss ...	—	—	—	(3,758)	(3,758)
Balance at December 31, 2001 .....	—	—	—	(4,811)	1,171
Issuance of common stock for cash	—	—	—	—	17
Issuance of Series B Convertible Preferred Stock net of issuance costs of \$136,000 .....	—	—	—	—	16,088
Conversion of Promissory Notes into Series B stock .....	—	—	—	—	653
Non-cash stock compensation .....	—	—	—	—	18
Issuance of common stock for license agreement .....	—	—	—	—	21
Issuance of options related to consulting agreement .....	—	—	—	—	1
Exercise of options to purchase common stock .....	—	(96)	—	—	6
Repurchase of common stock at ...	—	—	—	—	(2)
Net loss and comprehensive loss ...	—	—	—	(7,246)	(7,246)
Balance at December 31, 2002 .....	—	(96)	—	(12,057)	10,727
Issuance of Series B-2 Convertible Preferred Stock .....	—	—	—	—	10,524
Issuance of common stock for license agreement .....	—	—	—	—	24
Issuance of options related to consulting agreement .....	—	—	—	—	16
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	84
Exercise of options to purchase common stock .....	—	—	—	—	4
Repurchase of common stock .....	—	—	—	—	(1)
Deferred stock-based compensation related to issuance of stock options to employees .....	(1,595)	—	—	—	—
Amortization of stock-based compensation .....	155	—	—	—	155
Net loss and comprehensive loss ...	—	—	—	(13,255)	(13,255)
Balance at December 31, 2003 .....	(1,440)	(96)	—	(25,312)	8,278

**FAVRILLE, INC.**  
(a development stage company)  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
Period from January 21, 2000 (inception) to December 31, 2006  
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2003 .....	5,505,330	\$ 6	981,096	\$ 1	\$ 35,119
Issuance of options and warrant related to consulting agreement.....	—	—	—	—	169
Exercise of options to purchase common stock .....	—	—	889,266	1	555
Exercise of warrant to purchase common stock.....	—	—	9,638	—	6
Repurchase of common stock .....	—	—	(41,286)	—	(26)
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	36
Deemed dividend—beneficial conversion feature for Series C redeemable convertible preferred stock .....	—	—	—	—	28,103
Deferred stock-based compensation related to issuance of stock options to employees .....	—	—	—	—	9,362
Accretion of Series C redeemable Preferred Stock issuance costs .....	—	—	—	—	—
Amortization of stock-based compensation .....	—	—	—	—	—
Comprehensive Loss:					
Unrealized loss on cash equivalents and short-term investments .....	—	—	—	—	—
Net loss.....	—	—	—	—	—
Net comprehensive loss .....	—	—	—	—	—
Balance at December 31, 2004 .....	5,505,330	6	1,838,714	2	73,324
Issuance of common stock related to initial public offering and follow on offering, net of approximately \$4.6 million of issuance costs....	—	—	6,285,000	6	39,436
Deferred stock-based compensation related to issuance of stock options to employees.....	—	—	—	—	350
Deferred stock-based compensation related to cancellations of stock options to employees.....	—	—	—	—	(221)
Exercise of options to purchase common stock .....	—	—	13,126	—	9
Issuance of common stock related to Employee Stock Purchase Plan .....	—	—	27,050	—	106
Repurchase of common stock .....	—	—	(12,188)	—	(8)
Expiration of warrant.....	—	—	—	—	(27)
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	241
Conversion of Series C redeemable Preferred Stock to common stock .....	—	—	6,672,014	6	43,672
Conversion of preferred stock to common stock ...	(5,505,330)	(6)	5,505,330	6	—
Accretion of Series C redeemable Preferred Stock issuance costs .....	—	—	—	—	—
Amortization of stock-based compensation .....	—	—	—	—	—
Comprehensive Loss:					
Unrealized loss on cash equivalents and short-term investments .....	—	—	—	—	—
Net loss.....	—	—	—	—	—
Net comprehensive loss .....	—	—	—	—	—
Balance at December 31, 2005 .....	—	\$ —	20,329,046	\$ 20	\$ 156,882
Exercise of options to purchase common stock .....	—	—	90,262	—	57
Issuance of common stock related to Employee Stock Purchase Plan .....	—	—	94,302	1	355
Repurchase of common stock .....	—	—	(8,662)	—	(5)
Elimination of deferred compensation upon adoption of SFAS 123R .....	—	—	—	—	(5,655)
Stock-based compensation related to stock options to employees under SFAS 123R.....	—	—	—	—	4,010

Issuance of common stock related to PIPE, net of approximately \$450,000 of issuance costs .....	—	—	8,555,133	8	44,561
Sale of warrant to purchase common stock related to PIPE .....	—	—	—	—	374
Issuance costs related to Committed Equity					
Financing Facility.....	—	—	—	—	(82)
Payment of note receivable from stockholder.....	—	—	—	—	—
Comprehensive Loss:					
Unrealized gain on cash equivalents and short-term investments .....	—	—	—	—	—
Net loss.....	—	—	—	—	—
Net comprehensive loss .....	—	—	—	—	—
Balance at December 31, 2006 .....	—	\$ —	<u>29,060,081</u>	<u>\$ 29</u>	<u>\$ 200,497</u>

	Deferred Stock-Based Compensation	Note Receivable from Stockholder	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Balance at December 31, 2003 .....	\$ (1,440)	\$ (96)	\$ —	\$ (25,312)	\$ 8,278
Issuance of options and warrant related to consulting agreement.....	—	—	—	—	169
Exercise of options to purchase common stock .....	—	—	—	—	556
Exercise of warrant to purchase common stock .....	—	—	—	—	6
Repurchase of common stock .....	—	—	—	—	(26)
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	36
Deemed dividend-beneficial conversion feature for Series C redeemable convertible preferred stock .....	—	—	—	(28,103)	—
Deferred stock-based compensation related to issuance of stock options to employees .....	(9,362)	—	—	—	—
Accretion of Series C redeemable Preferred Stock issuance costs...	—	—	—	(51)	(51)
Amortization of stock-based compensation .....	2,416	—	—	—	2,416
Comprehensive Loss:					
Unrealized loss on cash equivalents and short-term investments .....	—	—	(2)	—	(2)
Net loss .....	—	—	—	(26,036)	(26,036)
Net comprehensive loss .....	—	—	—	—	(26,038)
Balance at December 31, 2004 .....	(8,386)	(96)	(2)	(79,502)	(14,654)
Issuance of common stock related to initial public offering and follow on offering, net of approximately \$4.6 million of issuance costs....	—	—	—	—	39,442
Deferred stock-based compensation related to issuance of stock options to employees .....	(350)	—	—	—	—
Deferred stock-based compensation related to cancellations of stock options to employees .....	221	—	—	—	—
Exercise of options to purchase common stock .....	—	—	—	—	9
Issuance of common stock related to Employee Stock Purchase Plan .	—	—	—	—	106
Repurchase of common stock .....	—	—	—	—	(8)
Expiration of warrant .....	—	—	—	—	(27)
Issuance of warrant in conjunction with credit agreement .....	—	—	—	—	241
Conversion of Series C redeemable Preferred Stock to common stock .....	—	—	—	—	43,678
Conversion of preferred stock to common stock .....	—	—	—	—	—
Accretion of Series C redeemable Preferred Stock issuance costs...	—	—	—	(6)	(6)
Amortization of stock-based compensation .....	2,860	—	—	—	2,860
Comprehensive Loss:					
Unrealized loss on cash equivalents and short-term investments .....	—	—	(52)	—	(52)
Net loss .....	—	—	—	(35,875)	(35,875)
Net comprehensive loss .....	—	—	—	—	(35,927)

Balance at December 31, 2005 .....	\$	(5,655)	\$	(96)	\$	(54)	\$	(115,383)	\$	35,714
Exercise of options to purchase common stock .....		—		—		—		—		57
Issuance of common stock related to Employee Stock Purchase Plan .....		—		—		—		—		356
Repurchase of common stock .....		—		—		—		—		(5)
Elimination of deferred compensation upon adoption of SFAS 123R .....		5,655		—		—		—		—
Stock-based compensation related to stock options to employees under SFAS 123R .....		—		—		—		—		4,010
Issuance of common stock related to PIPE, net of approximately \$450,000 of issuance costs .....		—		—		—		—		44,569
Sale of warrant to purchase common stock related to PIPE .....		—		—		—		—		374
Issuance costs related to Committed Equity Financing Facility .....		—		—		—		—		(82)
Payment of note receivable from stockholder .....		—		96		—		—		96
Comprehensive Loss:										
Unrealized gain on cash equivalents and short-term investments .....		—		—		57		—		57
Net loss .....		—		—		—		(40,511)		(40,511)
Net comprehensive loss .....		—		—		—		—		(40,454)
Balance at December 31, 2006 .....	<u>\$</u>	<u>—</u>	<u>\$</u>	<u>—</u>	<u>\$</u>	<u>3</u>	<u>\$</u>	<u>(155,894)</u>	<u>\$</u>	<u>44,635</u>

See accompanying notes.

**FAVRILLE, INC.**  
**(a development stage company)**  
**STATEMENTS OF CASH FLOWS**  
**(in thousands)**

	Years ended December 31,			Period from
	2006	2005	2004	January 21, 2000 (inception) to December 31, 2006
<b>Operating activities:</b>				
Net loss .....	\$ (40,511)	\$ (35,875)	\$ (26,036)	\$ (127,734)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization .....	2,133	1,825	1,426	6,491
Stock-based compensation .....	4,010	2,860	2,416	9,460
Amortization of premium/discount on short-term investments .....	(638)	6	(1)	(633)
Other .....	281	(566)	228	58
Changes in operating assets and liabilities:				
Other assets .....	105	329	(165)	(818)
Accounts payable and accrued liabilities .....	1,072	1,285	913	4,960
Deferred rent .....	1,443	527	596	2,763
Net cash used in operating activities .....	<u>(32,105)</u>	<u>(29,609)</u>	<u>(20,623)</u>	<u>(105,453)</u>
<b>Investing activities:</b>				
Purchases of property and equipment .....	(8,586)	(1,805)	(4,347)	(22,344)
Purchases of short-term investments .....	(63,386)	(32,995)	(1,493)	(97,874)
Maturities of short-term investments .....	58,348	12,003	—	70,351
Other assets .....	—	—	219	(70)
Restricted cash .....	(1,901)	56	52	(3,451)
Net cash used in investing activities .....	<u>(15,525)</u>	<u>(22,741)</u>	<u>(5,569)</u>	<u>(53,388)</u>
<b>Financing activities:</b>				
Proceeds from debt .....	7,563	5,300	3,675	22,970
Payments on debt .....	(3,113)	(5,499)	(2,119)	(12,196)
Issuance of preferred stock, net .....	—	—	43,621	76,144
Deferred IPO issuances costs, net .....	—	—	(66)	—
Proceeds from issuance of convertible promissory note .....	—	—	—	650
Issuance of common stock and warrants .....	45,369	39,557	562	85,564
Repurchase of restricted common stock .....	(5)	(8)	(26)	(42)
Net cash provided by financing activities .....	<u>49,814</u>	<u>39,350</u>	<u>45,647</u>	<u>173,090</u>
Net (decrease) increase in cash and cash equivalents .....	2,184	(13,000)	19,455	14,249
Cash and cash equivalents at beginning of period .....	12,065	25,065	5,610	—
Cash and cash equivalents at end of period .....	<u>\$ 14,249</u>	<u>\$ 12,065</u>	<u>\$ 25,065</u>	<u>\$ 14,249</u>
<b>Supplemental disclosures of cash flow information:</b>				
Cash paid for interest .....	<u>\$ 703</u>	<u>\$ 654</u>	<u>\$ 732</u>	<u>\$ 2,183</u>
<b>Supplemental non-cash financing activities:</b>				
Issuance of warrant related to line of credit agreement .....	<u>\$ —</u>	<u>\$ 241</u>	<u>\$ 36</u>	<u>\$ 383</u>
Issuance of options and warrant related to consulting agreement .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 169</u>	<u>\$ 186</u>
Issuance of preferred stock upon conversion of promissory note .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 650</u>
Issuance of restricted common stock for license agreements .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 45</u>

Deemed dividend—beneficial conversion feature for Series C redeemable convertible preferred stock.	\$ —	\$ —	\$ 28,103	\$ 28,103
Accretion of Series C redeemable convertible preferred stock issuance costs.....	\$ —	\$ 6	\$ 51	\$ 57
Conversion of Series C to common stock.....	\$ —	\$ 43,678	\$ —	\$ 43,678
Capitalized interest recorded as property, plant and equipment .....	\$ 91	\$ —	\$ —	\$ 91
Accrued asset acquisitions.....	\$ 1,819	\$ —	\$ —	\$ 1,819
Leasehold improvements acquired under tenant improvement allowance.....	\$ 7,382	\$ —	\$ —	\$ 7,382

See accompanying notes.

**Favrille, Inc.**  
**Notes to Financial Statements**

**1. Organization and Summary of Significant Accounting Policies**

***Organization and Business***

Favrille, Inc. (the Company or Favril) was incorporated in Delaware on January 21, 2000. The Company is a biopharmaceutical company focused on the research, development and commercialization of targeted immunotherapies for the treatment of cancer and other diseases of the immune system. The Company's lead product candidate, FavId, is based upon unique genetic information extracted from a patient's tumor. FavId is currently under investigation in a pivotal Phase 3 clinical trial for patients with follicular B-cell NHL and Phase 2 clinical trials in other B-cell NHL indications. The Company is developing additional applications based on its immunotherapy expertise and proprietary manufacturing technology, including a second product candidate, FAV-201, for the treatment of T-cell lymphoma.

The Company is a development stage company in the initial stage of its operations, and since inception, the Company has been engaged in organizational activities, including: recruiting personnel; establishing office and manufacturing facilities; conducting research and clinical development; and obtaining financing. From inception through December 31, 2006, the Company has incurred net losses of \$127.7 million and has a deficit accumulated during the development stage of approximately \$155.9 million.

***Financial Statements Preparation***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts in the Company's financial statements and the accompanying notes. Actual results could differ from those estimates. Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on reported results of operations.

***Cash Equivalents and Short-Term Investments***

Highly liquid investments and original maturities of three months or less, when purchased, are classified as cash and cash equivalents. Cash equivalents are comprised of commercial paper and U.S. government debt securities. The carrying amounts approximate fair value due to the short maturities of these instruments. Investments with maturities greater than three months when purchased are classified as short-term investments. All of the Company's short-term investments are classified as available-for-sale and are reported at fair value, as determined by quoted market prices, with any unrealized gains and losses, net of tax, recorded as a separate component of accumulated other comprehensive income (loss) in stockholders' equity. Unrealized gains and losses on investments accounted for all of the accumulated other comprehensive income (loss) balance in the Statement of Stockholders' Equity (Deficit). The Company manages its cash equivalents and short-term investments as a portfolio of highly marketable securities, all of which are intended to be available for the Company's current operations.

***Clinical Trial Accruals***

In the normal course of business, the Company contracts with numerous third-party clinical trial centers to perform various clinical trial activities in the on-going development of FavId. The financial terms of these agreements are subject to negotiation and variation from contract to contract may result in uneven payment flows. Payment under the contracts depend on factors such as the completion of individual patients' treatments and the related required documentation. These costs are a significant component of research and development expenses. The Company records expenses for contracted clinical trial costs based upon patient enrollment and the dates that they receive treatment. The Company obtains information regarding the numbers of patients enrolled and the numbers of treatments administered during each period through regular communication between its internal clinical trial personnel and the third-party clinical trial centers performing such enrollment and treatment. The objective of the accrual policy is to match the recording of expenses in the Company's financial statements to the actual services received and efforts expended, and the Company believes that its regular communications with third-party clinical trial centers regarding patient enrollment and treatment provide the most reliable basis for determining the timing and amount of expenses it records for clinical trial costs. Despite the Company's efforts to obtain accurate and current information from third-party clinical trial centers, the estimates may not match the timing of actual services performed by the clinical trial centers,

which may result in adjustments to the research and development expenses in future periods. However, to date there have been no material adjustments to clinical trial accruals in any of the periods presented, and the Company does not expect any material adjustments in future reporting periods.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to significant credit risk, consist primarily of cash and cash equivalents, short-term investments and restricted cash. The Company maintains cash deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. In addition, the Company invests in a variety of financial instruments and, by policy, limits the amount of credit exposure with any one issuer.

### ***Fair Value of Financial Instruments***

The carrying amount of cash equivalents, short-term investments, receivables, accounts payable and accrued expenses are considered to be representative of their respective fair value because of the short-term nature of those items. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of the long-term debt approximates its carrying value.

### ***Property and Equipment***

Property and equipment are stated on the basis of cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (three to seven years). Leasehold improvements are stated at cost and amortized over the shorter of the life of the lease term or the useful life of the asset.

### ***Capitalized Software***

In accordance with the Statement of Position, (SOP) No. 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*, the Company expenses costs as incurred for software developed for internal use incurred during the preliminary project stage and during the post-implementation/operation stage. Direct costs incurred during the application development stage, which provide additional functionality, are capitalized and are amortized on a straight-line basis over their estimated useful lives of five years, commencing on the date the software is placed into use.

### ***Impairment of Long-Lived Assets***

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. While the Company's current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value. Accordingly, there have been no indicators of impairment through December 31, 2006 or 2005.

### ***Deferred Rent***

Rent expense is recorded on a straight-line basis over the terms of the leases. The difference between rent expense and amounts paid under the lease agreements is recorded as deferred rent in the accompanying balance sheets. Tenant improvements paid by the landlord are capitalized as leasehold improvements and amortized over the shorter of their estimated useful lives or the remaining lease term, while the tenant improvement allowance is recorded as deferred rent and will be recovered ratably over the remaining term of the lease.

### ***Research and Development***

Research and development costs are expensed as incurred and consist primarily of costs associated with the clinical trials of the Company's product candidates, compensation and other expenses for research and development personnel, supplies, costs for consultants, facility costs and depreciation.

### **Patent Costs**

Costs related to filing and pursuing patent applications are expensed as incurred as recoverability of such expenditures is uncertain.

### **Comprehensive Income (Loss)**

In accordance with SFAS No. 130, *Reporting Comprehensive Income*, all components of comprehensive income (loss) are reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). The Company has disclosed its comprehensive income (loss) in the statement of stockholders' equity (deficit).

### **Stock-Based Compensation**

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," (SFAS 123(R)). Under SFAS 123(R), stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. The Company adopted the provisions of SFAS 123(R) using a modified prospective application. Accordingly, prior periods have not been revised for comparative purposes. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date, that are subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS 123, *Accounting for Stock-Based Compensation*. For further discussion of the adoption of SFAS 123(R) refer to Note 5 of the Financial Statements.

The Company has elected the FASB Staff Position No. SFAS 123(R)-3, "*Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*" (SFAS 123(R)-3). Under this method, the Company has elected to adopt the alternative transition method, which includes a simplified method to establish the beginning balance of the additional paid-in-capital pool related to the tax effects of employee stock-based compensation, that is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

### **Income Taxes**

In accordance with SFAS No. 109, *Accounting for Income Taxes*, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured on the balance sheet date based upon enacted tax rates, which will be in effect when these differences reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted. A valuation allowance is established when necessary to reduce deferred tax assets when it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. A full valuation allowance was recorded on the Company's net deferred tax assets as of December 31, 2006 and 2005, due to uncertainties related to the Company's ability to utilize deferred tax assets in the foreseeable future. These deferred tax assets primarily consist of certain net operating loss carryforwards and research and development tax credits.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. At this time, the Company believes it has appropriate support for the positions taken on its tax returns.

### **Net Loss per Common Share**

Net loss per share is calculated in accordance with SFAS No. 128, *Earnings Per Share* and Staff Accounting Bulletin (SAB) No. 98. Basic loss per share is calculated using the weighted average number of common shares outstanding during each period, without consideration for common stock equivalents. Diluted loss per share includes the dilutive effect of common equivalent shares outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

	As of December 31,		
	2006	2005	2004
<b>Historical outstanding antidilutive securities not included in diluted net loss per share calculation:</b>			
Common stock equivalents:			
Redeemable convertible preferred stock.....	—	—	6,672,014
Convertible preferred stock .....	—	—	5,505,330
Stock warrants .....	3,371,787	127,499	47,057
Options to purchase common stock .....	2,365,384	1,682,237	959,753
Common stock subject to repurchase .....	107,399	288,683	599,325
	<u>5,844,570</u>	<u>2,098,419</u>	<u>13,783,479</u>

### **Segment Information**

The Company adopted the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. SFAS No. 131 requires public companies to report financial and descriptive information about their reportable operating segments. The Company identifies its operating segments based on how management internally evaluates separate financial information, business activities and management responsibility. The Company believes it operates in a single business segment, therefore this standard did not have a material impact on the Company's financial statements.

### **Recent Accounting Pronouncements**

In September 2006, the Securities Exchange Commission ("SEC") issued Staff Accounting Bulletin ("SAB") 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, to address diversity in practice regarding consideration of the effects of prior year errors when quantifying misstatements in current year financial statements. The SEC concluded that registrants should quantify financial statement errors using both a balance sheet approach and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 states that if correcting an error in the current year materially affects the current year's statement of operations, the prior period financial statements must be restated. SAB 108 is effective for fiscal years ending after November 15, 2006 and was first effective for the Company for the year ended December 31, 2006. The adoption of SAB 108 did not significantly affect our financial condition or results of operations, financial position or cash flows.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and will first be effective for the Company for the year beginning January 1, 2008. The Company is in the process of analyzing the effects of this pronouncement.

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 will be effective for fiscal years beginning after December 15, 2006 and will first be effective for the Company for the year beginning January 1, 2007. The Company is currently evaluating the impact of FIN 48 on results of operations, financial position and cash flows.

## 2. Financial Statement Information

### Short-term Investments

Short-term investments by security type were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2006:</b>				
Government Agency Securities .....	\$ 598	\$ —	\$ —	\$ 598
Corporate Bonds and Notes .....	21,962	4	—	21,966
Asset-Backed Securities .....	2,395	—	(1)	2,394
Certificate of Deposit .....	3,202	—	—	3,202
Total .....	<u>\$ 28,157</u>	<u>\$ 4</u>	<u>\$ (1)</u>	<u>\$ 28,160</u>
<b>December 31, 2005:</b>				
Government Agency Securities .....	\$ 10,427	\$ —	\$ (31)	\$ 10,396
Corporate Bonds and Notes .....	8,784	—	(14)	8,770
Asset-Backed Securities .....	3,270	—	(9)	3,261
Total .....	<u>\$ 22,481</u>	<u>\$ —</u>	<u>\$ (54)</u>	<u>\$ 22,427</u>

All investments that have gross unrealized losses have been held for less than twelve months. At December 31, 2006 the Company had a net unrealized gain on short-term investments of approximately \$3,000. At December 31, 2005, the Company had an unrealized loss on short-term investments of approximately \$54,000. These unrealized gains and losses are included in the statement of stockholders' equity as other comprehensive income and loss. Contractual maturities of short-term investments are due in one year or less. There have been no significant realized gains or losses on investments since the inception of the Company.

### Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2006	2005
Lab equipment .....	\$ 3,570	\$ 3,749
Manufacturing equipment .....	2,968	2,998
Computer, software and office equipment .....	3,384	2,606
Leasehold improvements .....	4,817	4,299
Construction in process .....	16,197	7
	30,936	13,659
Accumulated depreciation and amortization .....	(5,865)	(4,229)
	<u>\$ 25,071</u>	<u>\$ 9,430</u>

Total depreciation expense, including amortization for assets under capital lease, for the years ended December 31, 2006, 2005 and 2004, and the period from January 21, 2000 (inception) to December 31, 2006 was \$2.1 million, \$1.8 million, \$1.4 million and \$6.5 million, respectively. As of December 31, 2006, approximately \$4.3 million of unamortized capitalized software costs were included in construction in process.

### **Accounts Payable and Accrued Liabilities**

Accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31,	
	2006	2005
Accounts payable.....	\$ 1,230	\$ 1,295
Accrued clinical trial costs.....	558	825
Accrued compensation.....	2,288	832
Accrued liabilities.....	2,703	936
	<u>\$ 6,779</u>	<u>\$ 3,888</u>

### **3. Commitments and Contingencies**

#### ***Equipment Lines of Credit***

During December 2005, the Company entered into loan and security agreement with a lender and an amendment to a loan and security agreement with another lender (Agreements) under which the lenders agreed to extend to the Company a line of credit equal to \$20.0 million. As a condition of the Agreements, on December 30, 2005, the Company borrowed \$3.0 million against the line of credit to repay the outstanding balance of existing loan and security agreements executed in March 2003. The Agreements state that the remaining proceeds are to be used solely for the purchase of eligible equipment and certain leasehold improvements through December 2007. Borrowings against the line of credit will be structured as promissory notes with the interest rate fixed at the time of each draw based on the three-year treasury bill. Such borrowings are to be secured by all existing and future assets of the Company, excluding intellectual property, and repaid, monthly, over 36 to 42 months, depending upon the nature of the equipment financed. The Company has agreed not to pledge its intellectual property to any third party or permit a third party to restrict the Company's ability to pledge its intellectual property. However, the Company retains the right to grant non-exclusive licenses of its intellectual property in the ordinary course of business and non-exclusive and exclusive licenses of its intellectual property in connection with joint ventures and corporate collaborations in the ordinary course of business. The Agreements contain a restrictive financial covenant requiring the Company maintain a minimum of \$15.0 million in available cash, cash equivalent and short-term investments. In addition, the Agreements subject the Company to certain non-financial covenants. As of December 31, 2006, the Company was in compliance with the terms of the Agreements. As of December 31, 2006 and 2005, the Company had borrowings outstanding under the loan and security agreement totaling approximately \$8.7 million and \$3.0 million, respectively. Borrowings under the line of credit bore interest at rates ranging from 11.45% to 12.17% per annum.

During July 2004, the Company entered into a loan and security agreement under which the lender agreed to extend to the Company a line of credit equal to \$2.5 million. In June 2005, the lender increased the line of credit by \$1.6 million, which created a total line of credit facility of \$4.1 million. The proceeds were used solely for the purchase of eligible equipment, leasehold improvements and software. Borrowings under the line of credit bear interest at 9.34% and 10.93% per annum and are collateralized by certain of the financed equipment. Principal and interest, related to each draw, are payable monthly over 36 months or 42 months. The loan and security agreement subjects the Company to certain financial and non-financial covenants. As of December 31, 2006, the Company was in compliance with the terms of the loan and security agreement. As of December 31, 2006 and 2005, the Company had borrowings outstanding under the loan and security agreement totaling \$2.0 million and \$3.3 million respectively.

During March 2003, the Company entered into a loan and security agreement under which the lender agreed to extend to the Company a line of credit equal to \$7.0 million. Borrowings under the line of credit bore interest at rates ranging from 11.44% to 14.66% per annum and were collateralized by certain items of the financed equipment and leasehold improvements. Principal and interest, related to each draw, were payable monthly over 36 months or 42 months, and the Company was required to make final terminal payments equal to 7.50% or 12.75% of the original principal amount of each drawdown. Monthly payments were made from time of each drawdown through November 2005. In December 2005, the Company repaid all of the outstanding principal and interest of approximately \$2.9 million, of which approximately \$200,000 had been prepaid at the time of the borrowings and an early termination fee of approximately \$290,000, which the Company recorded as a loss on extinguishment of debt.

Future minimum principal payments due under the above loan and security agreements are as follows at December 31 (in thousands):

2007 .....	\$ 5,070
2008 .....	3,216
2009 .....	2,250
2010 .....	287
Total .....	10,823
Less: Amounts representing debt discount .....	(93)
Net loan .....	10,730
Less: Current portion .....	4,976
Long-term portion .....	<u>\$ 5,754</u>

### Leases

In November 2005, the Company entered into an amended and restated lease agreement (Lease Agreement) with its landlord to expand its existing facility to support commercial-scale manufacturing of FavId. This 80,000-square foot facility (Existing Facility) will be devoted to manufacturing and research and development. The landlord will provide the Company with a tenant improvement allowance of \$10 million for the Existing Facility. In September 2006, the Company entered into the First Amendment to the Amended and Restated Office Lease Agreement (Amendment) pursuant to which the Company agreed to expand the Existing Premises to include an adjacent 48,000-square foot facility (New Facility) to house the Company's corporate headquarters and warehousing operations. The landlord will provide the Company with a tenant improvement allowance of \$1.2 million for the New Facility. The Amendment was effective December 1, 2006, with a commencement date of March 1, 2007 (ninety-one days after the effective date). The landlord has incurred approximately \$7.4 million in costs through December 31, 2006.

**Existing Facility** Under the Lease Agreement, monthly base rent for the Existing Facility will average approximately \$168,000 for the period November 2005 through January 2007. Monthly rent will be approximately \$288,000 per month beginning in February 2007 and then will increase by 3.5% annually commencing in February 2008. The Lease Agreement further required the Company to increase the security deposit provided to the landlord from approximately \$166,000 to approximately \$355,000, upon execution of the Lease Agreement. In addition, prior to any distribution of the tenant improvement allowance, the Company was required to deliver to the landlord an amendment to the existing letter of credit to increase the amount from approximately \$1.6 million to approximately \$3.5 million, which amount will be subject to increases, reductions and reinstatements under specified circumstances. The Company is responsible for all operating costs and real estate taxes incurred with respect to the Existing Facility and is required to maintain insurance at specified minimum levels during the term of the Lease Agreement. In addition, the Company is obligated to pay the landlord monthly management fees equal to 2.25% of the applicable base rent during the term of the Lease Agreement and an additional fee equal to 1% of the construction costs incurred in connection with tenant improvements.

Unless earlier terminated, the Lease Agreement will expire June 30, 2025, but the Company has the option to extend the term of the Lease Agreement for two additional five-year periods. Construction of the tenant improvements began in June 2006.

**New Facility** Under the Amendment, rental payments for the New Facility begin on March 1, 2007, with the base rent for the New Facility increasing by 3.5% annually commencing on March 2008. However, during the first 12 months of the lease for the New Facility, the Company is obligated to pay only 50% of the base rent and operating expenses attributable to the New Facility. The provisions of the Lease Agreement related to the Existing Premises regarding operating costs, real estate taxes, insurance, monthly management fees and tenant improvement fees will also apply to the New Facility. Unless earlier terminated, the Company's lease of the New Facility will expire on June 30, 2025, but the Company has the option to extend the term of the lease for two additional five-year periods. The Company has a one-time right to terminate its lease of the New Facility effective as of June 1, 2017, upon six months' prior notice to the landlord.

In January 2003, the Company entered into a 15 and one-half year lease for approximately 49,000 square feet of manufacturing, laboratory and office space (Original Lease). The Original Lease had stated rental increases over the lease term. Under the terms of the Original Lease agreement, the Company was required to pay a security deposit of approximately \$152,000 and execute a \$1.6 million letter of credit in favor of the landlord, which is secured by a restricted investment in money market funds. The restricted investment is included in restricted cash in the accompanying balance sheets. The Original Lease required the Company to pay for its share of maintenance, insurance and property taxes. In July 2004, the

Company amended its Original Lease to add an additional 14,000 square feet of office space. The lease term on the additional space was to expire July 31, 2008, but could be extended at the Company's option for two additional two year periods. In August 2005, the Company amended the Original Lease to add the remaining 17,000 square feet of space in order to occupy the entire building. The lease term on the additional space was to expire on January 31, 2007. In November 2005, the Company terminated the Original Lease and all amendments thereto upon executing an amended and restated Lease Agreement as noted above.

In May 2003, the Company entered into a 36-month capital lease for the purchase of certain property and equipment. The lease bears an annual interest rate of 6.57%, with interest and principal due monthly. In January 2004, the Company entered into two capital leases, for the purchase of certain property and equipment, with terms of 60 months and 36 months, respectively. The capital leases bear effective annual interest rates of 5.18% and 21.67%, respectively, with interest and principal due monthly.

Future annual minimum payments under non-cancelable operating leases are as follows at December 31 (in thousands):

	<u>Operating Leases</u>
2007 .....	\$ 3,693
2008 .....	4,335
2009 .....	4,557
2010 .....	4,717
2011 .....	4,882
Thereafter.....	74,689
Total minimum lease payments .....	<u>\$ 96,873</u>

The Company records rental expense on a straight-line basis over the term of the lease. Rental expense, including equipment rental, for the years ended December 31, 2006, 2005 and 2004, and the period from January 21, 2000 (inception) to December 31, 2006 and was \$3.6 million, \$2.4 million, \$2.5 million and \$10.7 million, respectively.

The landlord tenant improvement allowances of \$10.0 million and \$1.2 million associated with the expansion of the Existing Facility and the build out of the New Facility, respectively, will be capitalized as leasehold improvements and amortized over the shorter of their estimated useful lives or the remaining lease term, while the tenant improvement allowance is recorded as deferred rent and will be recovered ratably over the remaining term of the lease.

#### 4. License Agreements

In November 2004, the Company entered into a supply and license agreement with one of its vendors and made a \$50,000 milestone payment, upon execution of the agreement. In October 2006, the Company made an additional payment of \$50,000 for the achievement of a subsequent milestone. An additional aggregate of up to \$250,000 will be due upon the achievement of certain milestones, the timing of which is not known at this time. The initial term of the agreement is 96 months and is automatically renewable for 12 month periods unless terminated by written notice by either party. Either party may terminate the agreement earlier upon a breach by the other party that is not cured within 60 days or other events relating to insolvency or bankruptcy. The payments were recorded as license fees and are amortized to research and development expense over the term of the agreement. During 2005, the Company purchased the required minimum raw material under the agreement. Expense related to the amortization of the license and minimum purchase requirement for the years ended December 31, 2006 and 2005 and the period from January 21, 2000 (inception) to December 31, 2006 totaled approximately \$11,000, \$241,000 and \$253,000, respectively.

In December 2003, the Company entered into a non-exclusive worldwide fee-bearing royalty-free license agreement for certain patent rights. In consideration for the patent rights, the Company paid an initial fee of \$20,000 and the first annual payment of \$10,000 upon execution of the agreement in 2003 and is committed to annual payments of \$10,000 through the Company's clinical development period (anticipated to end in 2008) and, after commercialization of its first product candidate, an aggregate of \$225,000 in annual fees and a milestone payment. The annual payment is recorded as research and development expense. The initial fee has been recorded as a license fee and is amortized to research and development expense over a five-year period, the estimated life of the technology. Expense related to the license agreement for the years

ended December 31, 2006, 2005 and 2004 and the period from January 21, 2000 (inception) to December 31, 2006 totaled approximately \$14,000, \$14,000, \$14,000 and \$43,200, respectively.

##### **5. Change in Accounting Method for Stock-Based Compensation**

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," (SFAS 123(R)). SFAS 123(R) requires the recognition of the fair value of stock-based compensation in net income or loss. The Company recognizes the stock-based compensation expense over the requisite service period of the individual grantees on a straight-line basis over the vesting period, which is generally four years. Prior to January 1, 2006, the Company recorded compensation expense for stock options based upon their intrinsic value on the date of grant pursuant to Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees (APB 25)*. Prior to the Company's initial public offering (IPO), the Company established the exercise price based on the fair value of the Company's stock at the date of grant as determined by the Board of Directors (the Board). Therefore, the options had no intrinsic value upon grant and no expense was recorded upon issuance. With respect to certain options granted during 2005 and 2004, the Company had recorded deferred compensation of \$350,000 and \$9.4 million, respectively, for the incremental difference at the grant date between the fair value per share determined by the Board and the deemed fair value per share determined solely for financial reporting purposes.

The Company has elected the modified prospective transition method for adopting SFAS 123(R). Under this method, the provisions of SFAS 123(R) apply to all awards granted or modified after the date of adoption. The deferred stock-based compensation balance of \$5.7 million as of December 31, 2005, which was accounted for under APB 25, was reclassified as a reduction of additional paid-in capital upon the adoption of SFAS 123(R). In addition, the unrecognized expense of awards not yet vested at the date of adoption will be recognized in net income or loss in the periods after the date of adoption using the same Black-Scholes valuation method and assumptions determined under the original provisions of SFAS 123, "Accounting for Stock-Based Compensation," as disclosed in our quarterly and annual reports. The cumulative effect of the change in accounting principle from APB 25 to SFAS 123(R) was not material, because the amortization of expense related to options granted prior to the adoption was based on the single-option approach.

##### ***Stock-Based Compensation under SFAS 123(R)***

The Company estimates the fair value of each stock-based award on the grant date using the Black-Scholes valuation model. To facilitate the adoption of SFAS 123(R), the Company applied provisions of Staff Accounting Bulletin (SAB) 107 in developing its methodologies to estimate our Black-Scholes valuation model inputs. Option valuation models, including Black-Scholes, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. Below is a summary of the methodologies the Company utilized to estimate the assumptions:

***Valuation and Amortization Method*** – The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing formula and a single-option award approach. This fair value is then amortized on a straight-line basis over the requisite service period, which is generally the vesting period.

***Expected Term***- The expected term of the Company's stock-based awards represents the period that the Company's stock-based awards are expected to be outstanding and is determined based on the SAB 107 simplified method, since the Company does not have adequate history of exercises of its stock-based awards since its IPO in February 2005.

***Expected Volatility***- The Company estimates its volatility factor by using the historical average volatility, over a period equal to the expected term, of comparable companies since it does not have adequate stock price history of its own stock to determine volatility.

***Expected Dividend*** - The Black-Scholes valuation model calls for a single expected dividend yield as an input. The dividend yield of zero is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends in the future.

***Risk-Free Interest Rate*** – The Company bases the risk-free interest rate used in the Black-Scholes valuation model on the implied yield currently available on the U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of the Company's stock-based awards does not correspond with the terms for which interest rates are quoted, the Company performs a straight-line interpolation to determine the rate from the available maturities.

*Estimated Forfeitures* – When estimating forfeitures, the Company considers voluntary termination behavior as well as an analysis of actual option forfeitures. As stock-based compensation expense recognized in the Statement of Operations for the year ended December 31, 2006 is based on awards ultimately expected to vest, it should be reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated based on historical experience. In the Company's pro forma information required under SFAS 123 for the periods prior to January 1, 2006, the Company accounted for forfeitures as they occurred.

*Fair Value* – The fair value of the Company's stock options granted to employees and non-employee directors and employee stock purchase plan offerings for the years ended December 31, 2006, 2005 and 2004 was estimated using the following assumptions:

	Stock Option Plans			Employee Stock Purchase Plans		
	2006	2005	2004	2006	2005	2004
Weighted average risk-free interest rate	4.77%	4.30%	2.83%	4.99%	4.41%	N/A
Volatility .....	61.8%	70%	70%	57.6%	70%	N/A
Dividend yield.....	0%	0%	0%	0%	0%	N/A
Weighted average expected life (years).	6.25	4.0	4.0	1.25	1.8	N/A

### ***Stock-Based Compensation Expense***

Under provisions of SFAS 123(R), the Company recorded approximately \$4.0 million of stock-based compensation expense in our Statement of Operations for the year ended December 31, 2006. The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock-based compensation granted both before and after the adoption of SFAS 123(R). Prior to the adoption of SFAS 123(R), the Company recorded approximately \$2.9 million and \$2.4 million of stock-based compensation for certain options granted during 2005 and 2004 in our Statement of Operations for the years ended December 31, 2005 and 2004, respectively, under the provisions of APB 25 based upon their intrinsic value. Total stock-based compensation expense recognized for the years ended December 31, 2006, 2005 and 2004 was as follows (in thousands, except per share data):

	2006	2005	2004
Research and development.....	\$ 1,961	\$ 1,406	\$ 1,196
General and administrative .....	2,049	1,453	1,220
Stock-based compensation expense .....	<u>\$ 4,010</u>	<u>\$ 2,859</u>	<u>\$ 2,416</u>

At December 31, 2006, the total compensation cost related to unvested stock-based awards granted to employees under the Company's stock award plans but not yet recognized was approximately \$6.7 million, net of estimated forfeitures of approximately \$380,000. This cost will be amortized on a straight-line basis over a weighted-average period of approximately 1.25 years and will be adjusted for subsequent changes in estimated forfeitures.

The Company has a net operating loss carry-forward as of December 31, 2006, and no excess tax benefits for the tax deductions related to share based awards were recognized in the statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in 2006 that would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities.

## Pro-forma Disclosures

SFAS 123(R) requires the Company to present pro forma information for the comparative period prior to adoption as if it had accounted for all our stock options under the fair value method of the original SFAS 123. The following table illustrates the effect on net loss and earnings per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation to the same period in the prior years (in thousands, except per share data):

	Years ended December 31,	
	2005	2004
Net loss applicable to common stockholders as reported.....	\$ (35,881)	\$ (54,190)
Add: Stock-based employee compensation expense included in net loss.....	2,860	2,416
Deduct: Stock-based employee compensation expense determined under fair value method for all awards.....	<u>(3,217)</u>	<u>(2,564)</u>
Pro forma net loss applicable to common stockholder .....	<u>\$ (36,238)</u>	<u>\$ (54,338)</u>
Net loss per share:		
As reported—Basic and Diluted .....	<u>\$ (1.99)</u>	<u>\$ (51.48)</u>
Pro forma—Basic and Diluted.....	<u>\$ (2.01)</u>	<u>\$ (51.62)</u>

As a result of adopting SFAS 123(R), the Company's net loss for the year ended December 31, 2006 is approximately \$1.3 million larger than if the Company had continued to account for stock-based compensation under APB 25. Basic and diluted net loss per share is \$0.05 higher than if the Company had continued to account for stock-based compensation under APB 25.

The Company accounts for stock option grants and similar equity instruments granted to non-employees under the fair value method, in accordance with Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and SFAS No. 123.

## 6. Stockholders' Equity

### Committed Equity Financing Facility

On December 19, 2006, the Company entered into a Committed Equity Financing Facility ("CEFF") with Kingsbridge Capital Limited ("Kingsbridge") pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of 5.8 million shares of the Company's common stock or an aggregate of \$40 million during the next three years. The Company may require Kingsbridge to purchase newly-issued shares of the Company's common stock at a price between 90% and 94% of the volume-weighted average price on each trading day during an eight-day pricing period. The maximum dollar amount of shares that the Company may require Kingsbridge to purchase in any such pricing period is the lesser of \$10 million or 1.75% of the Company's market capitalization at the time of a draw down under the CEFF. The Company is not obligated to sell any of the \$40 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. As of December 31, 2006, no shares have been sold to Kingsbridge.

In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase 250,000 shares of the Company's common stock at an exercise price of \$3.98 per share (the "Warrant"). The Warrant is exercisable beginning six months after the date of issuance and for a period of five years thereafter.

On February 15, 2007, the Company filed a resale registration statement with the Securities and Exchange Commission ("SEC") with respect to resale shares of common stock pursuant to the CEFF and underlying warrant. To date no securities have been issued pursuant to this registration statement.

### Registration Statement

On June 20, 2006, the Company filed a shelf registration statement on Form S-3 with the Securities Exchange Commission. The shelf registration statement on Form S-3 permits the Company to sell, in one or more public offerings,

shares of its common stock, debt securities or warrants, or any combination of such securities, for proceeds in an aggregate amount of up to \$60 million.

#### ***Private Placement of Common Stock and Warrants***

On March 6, 2006, the Company entered into a securities purchase agreement relating to a private placement in which the Company issued and sold to certain investors, for an aggregate purchase price of approximately \$45.4 million, 8.6 million shares of its common stock and warrants to purchase up to 3 million shares of its common stock at an exercise price of \$5.26 per share. At the closing, investors in the private placement paid \$5.26 per share of common stock and an additional purchase price equal to \$0.125 per warrant.

Certain of the Company's existing stockholders, including two members of our board of directors, Ivor Royston, M.D. and Fred Middleton, and funds affiliated with Forward Ventures, Sanderling Ventures, Alloy Ventures and William Blair Capital Partners, invested in the private placement. Dr. Royston, Mr. Middleton, Doug Kelly, M.D. and Arda Minocherhomjee, Ph.D., members of our board of directors on March 6, 2006, are associated with Forward Ventures, Sanderling Ventures, Alloy Ventures and William Blair Capital Partners, respectively.

The Company filed a registration statement with the Securities and Exchange Commission on March 31, 2006 covering the resale of the shares of common stock issued in the private placement and the shares of common stock issuable upon exercise of the warrants issued in the private placement.

#### ***Initial Public Offering***

On February 7, 2005, the Company completed an initial closing of its initial public offering (IPO) in which it sold 6,000,000 shares of common stock for proceeds of \$37.7 million, net of underwriting discounts and commissions and \$1.4 million of offering expenses. In addition, on March 7, 2005, the Company completed an additional closing of its IPO in which it sold an additional 285,000 shares of common stock pursuant to the partial exercise by the underwriters of an over-allotment option which resulted in proceeds of \$1.8 million, net of underwriting discounts and commissions.

#### ***Authorized Capital Stock***

On February 7, 2005, the Company filed an amended and restated certificate of incorporation to provide for authorized capital stock of 75,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

#### ***Convertible Preferred Stock***

Effective immediately prior to the initial closing of the IPO in February 2005, shares of Series A, B, B-2 and C convertible preferred stock then outstanding were converted into an aggregate of 12,177,344 shares of the Company's common stock.

#### ***Series C Redeemable Convertible Preferred Stock Deemed Dividend***

The 2004 Series C financing, involved the sale of preferred stock at a price per share below the Company's anticipated initial public offering price. Accordingly, pursuant to EITF 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, the Company recorded a deemed dividend on the Series C shares of \$28.1 million, which is the difference in the gross proceeds from the Series C offering and the underlying value of the conversion shares (adjusted for a conversion price adjustment feature). The \$28.1 million deemed dividend has been entirely recognized in the year ended 2004, as an adjustment to the net loss applicable to common stockholders since the preferred stock was convertible, at any time, at the option of the holder, and was not mandatorily redeemable. In accordance with EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, the Company calculated the deemed dividend of \$28.1 million using the most favorable conversion price of \$6.33 per conversion share.

#### ***Restricted Stock***

In January 2000, the Company issued approximately 396,000 restricted shares of the Company's common stock to certain employees with vesting over a three-year period. During 2002 and 2001, the Company issued an additional 9,638 and 50,119, respectively, of restricted shares of common stock to certain directors and consultants. The restricted stock vests

monthly, over a period of two to four years. In addition, during 2006, 2005, 2004 and the period from January 21, 2000 (inception) to December 31, 2006, the Company issued none, 1,536, 706,268 and 942,950 shares, respectively, of restricted shares of common stock upon the early exercise of stock options, as noted below. The options generally vest over four years. Included in the restricted stock issued in 2002 are 185,060 shares of common stock issued upon the early exercise of options by an officer of the Company through a full recourse promissory note for \$96,000. The note receivable from stockholder had a maturity date of April 19, 2006 and was paid in full at that time. During the years ended December 31, 2006, 2005, 2004 and the period from January 21, 2000 (inception) to December 31, 2006, the Company repurchased 8,666, 12,188, 41,286 and 67,743 unvested shares, respectively. As of December 31, 2006 and 2005, 107,399 shares and 288,683 shares, respectively, were unvested and subject to repurchase by the Company.

### ***Stock Options***

Under the Amended and Restated 2001 Equity Incentive Plan (the Equity Incentive Plan), the Company is authorized to issue approximately 3.8 million shares of common stock under various instruments. Options granted under the Equity Incentive Plan generally expire no later than ten years from the date of grant (five years for a 10% stockholder). Options generally vest over a period of four years. Prior to the Company's IPO in February 2005, all options granted under the Equity Incentive Plan allowed for early exercise prior to the option becoming fully vested. On the first day of each fiscal year, beginning in 2006, the share reserve under the Equity Incentive Plan is automatically increased by the number of shares equal to the least of: i) 5% of the Company's outstanding shares of Common Stock on the day preceding the first day of such fiscal year; ii) 1.3 million shares of common stock; or iii) an amount determined by the Board.

In December 2004, the Board approved the 2005 Non-Employee Directors' Stock Option Plan (the Directors' Plan), which became effective on the closing date (February 7, 2005) of the registration statement filed in connection with the Company's IPO and was amended in June 2006. The Directors' Plan provides for the automatic grant of non-statutory options to purchase shares of common stock to non-employee directors. An aggregate of 420,000 shares of common stock have been reserved for future issuance under the Directors' Plan. This amount may be increased annually on the first day of the Company's fiscal year, from 2005 to 2013, by the lesser of 90,000 shares of common stock or an amount determined by the Board. In 2006, the Board did not increase the shares reserved for future issuance.

The exercise price of incentive stock options must be equal to at least the fair value of the Company's common stock on the date of grant, and the exercise price of non-statutory stock options may be no less than 85% of the fair value of the Company's common stock on the date of grant. The exercise price of any option granted to a 10% stockholder may not be less than 110% of the fair value of the Company's common stock on the date of grant.

The following table summarizes the Company's stock option activity for employee and director stock options (shares in thousands):

	Shares	Approximate Weighted- average exercise price	Weighted Average Remaining Contractual Term (in Years)	Average Intrinsic Value (in thousands)
Outstanding at December 31, 2000.....	—	\$ —		
Granted .....	69	0.52		
Exercised .....	(39)	0.52		
Cancelled/Forfeited.....	—	—		
Outstanding at December 31, 2001.....	30	0.52		
Granted .....	361	0.57		
Exercised .....	(196)	0.53		
Cancelled/Forfeited.....	(4)	0.54		
Outstanding at December 31, 2002.....	191	0.61		
Granted .....	312	0.63		
Exercised .....	(6)	0.60		
Cancelled/Forfeited.....	(28)	0.62		
Outstanding at December 31, 2003.....	469	0.62		
Granted .....	1,389	0.64		
Exercised .....	(889)	0.63		
Forfeited.....	(10)	0.62		
Expired.....	—	—		
Outstanding at December 31, 2004.....	959	0.63		
Granted .....	792	4.74		
Exercised .....	(13)	3.36		
Forfeited.....	(56)	2.56		
Expired.....	—	—		
Outstanding at December 31, 2005.....	1,682	2.50		
Granted .....	923	6.45		
Exercised .....	(90)	0.65		
Forfeited.....	(132)	4.42		
Expired.....	(18)	5.40		
Outstanding at December 31, 2006.....	<u>2,365</u>	<u>\$ 3.99</u>	<u>8.34</u>	<u>\$ 1,498</u>
Vested and expected to vest at December 31, 2006 .....	<u>2,301</u>	<u>\$ 3.95</u>	<u>8.33</u>	<u>\$ 1,485</u>
Exercisable at December 31, 2006.....	<u>1,166</u>	<u>\$ 1.99</u>	<u>8.34</u>	<u>\$ 1,498</u>
Exercisable at December 31, 2005.....	<u>995</u>	<u>\$ 0.90</u>		
Exercisable at December 31, 2004.....	<u>959</u>	<u>\$ 0.63</u>		

The weighted-average fair value of options granted during 2006, 2005 and 2004, and for the period from January 31, 2000 (inception) to December 31, 2006 was \$4.02, \$2.85, \$6.88 and \$4.61, respectively. At December 31, 2006 and 2005, 1,165,525 and 994,942 outstanding options were exercisable, respectively. In 2004, all outstanding options were exercisable, and options to purchase 226,477 were vested.

The intrinsic value of stock options at the date of exercise is the difference between the fair value of the stock at the date of exercise and the exercise price. During the years ended December 31, 2006, 2005, and 2004, the total intrinsic value of options exercised was \$327,692, \$34,995 and \$16,764, respectively. In determining the intrinsic value of stock options exercised prior to the IPO in February 2005, the Company established the exercise price based on the fair value of the Company's stock at the date of grant as determined by the Board. Aggregate intrinsic value is calculated as the difference

between the exercise price of the underlying awards and the quoted price of the Company's common stock for the 804,000 options that were in-the-money as of December 31, 2006.

Shares available for future stock option grants under the Equity Incentive Plan and the Directors' Plan were 631,508 at December 31, 2006. At December 31, 2005, the Company had issued more shares than available for future issuance or grant under the Equity Incentive Plan, creating a deficit of approximately 40,020 shares. The deficit was offset on January 1, 2006 as a result of an automatic increase to the share reserve of 1,016,452 shares. At December 31, 2004, 683,000 shares remained available for future issuance or grant under the Equity Incentive Plan.

The following table summarizes information as of December 31, 2006 concerning options outstanding:

Range of Exercise Prices .....	Options Outstanding			Options Exercisable	
	Options Outstanding	Weighted Average Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
\$0.52 - \$0.73 .....	804,200	7.19	\$ 0.64	804,200	\$ 0.63
\$0.74 - \$4.60 .....	396,883	9.11	\$ 3.97	123,544	\$ 4.11
\$4.61 - \$5.50 .....	475,930	8.43	\$ 5.37	216,554	\$ 5.46
\$5.51 - \$7.05 .....	184,355	8.72	\$ 5.72	21,227	\$ 5.65
\$7.06 - \$7.40 .....	504,016	9.22	\$ 7.40	—	\$ —
<u>\$0.52 - \$7.40 .....</u>	<u>2,365,384</u>	<u>8.34</u>	<u>\$ 3.99</u>	<u>1,165,525</u>	<u>\$ 1.99</u>

### **Employee Stock Purchase Plan**

In December 2004, the Board approved the 2005 Employee Stock Purchase Plan (the Purchase Plan) which became effective on the closing date (February 7, 2005) of the registration statement filed in connection with the Company's IPO.

Under the Purchase Plan, the Company may issue up to 350,000 shares of common stock to eligible employees who elect to participate in the Purchase Plan. This amount will be increased annually on the first day of the Company's fiscal year, from 2005 to 2013, by the least of i) 2% of the Company's outstanding shares of Common Stock on the day preceding such fiscal year, ii) 50,000 shares of Common Stock or iii) an amount determined by the Board. In 2006, the Board approved an increase of 50,000 shares under the Purchase Plan. Employees participating in the Purchase Plan will obtain the right to purchase shares of Common Stock at the

lower of 85% of the Common Stock closing price on the first day of the offering period or 85% of the Common Stock closing price on the purchase date. The initial offering period commenced upon the closing date (February 7, 2005) of the Company's IPO and will be approximately 24 to 27 months in duration, with purchase dates occurring every six months. As of December 31, 2006 and 2005, employees had purchased 94,302 and 27,050 shares, respectively, of Common Stock under the Purchase Plan. At December 31, 2006, approximately 229,000 shares were reserved for future issuance and there was no aggregate intrinsic value of these reserved shares outstanding under the Purchase Plan.

### **Warrants**

In December 2006, in conjunction with a Committed Equity Financing Facility, or CEFF, the Company issued warrants to purchase up to 250,000 shares of the Company's Common Stock at an exercise price of \$3.98 per share. The warrant is exercisable beginning six months after the date of grant through June 19, 2012. The Company determined the fair value of the warrants on the grant date, using the Black-Scholes pricing model, of \$343,000 and recorded that amount in a contra-equity account. The assumptions used in determining the fair value of the warrants were a risk-free interest rate of 4.68%; dividend yield of 0%; expected volatility of 61.8%; and an expected life of five years and six months. As of December 31, 2006, the warrants remained outstanding.

In March 2006, in conjunction with a securities purchase agreement relating to a private placement of approximately \$45.4 million, the Company issued warrants to purchase up to 2,994,288 shares of the Company's Common Stock at an exercise price of \$5.26 per share. At the closing, investors in the private placement paid an additional purchase price equal to \$0.125 per share underlying the warrants. The warrants are exercisable through March 7, 2011. The Company determined the fair value of the warrants on the grant date, using the Black-Scholes pricing model, of \$8.9 million and recorded that amount in a contra-equity account which was deducted from the proceeds received. The assumptions used in determining the

fair value of the warrants were a risk-free interest rate of 4.76%; dividend yield of 0%; expected volatility of 61.8%; and an expected life of five years. As of December 31, 2006, the warrants remained outstanding.

In December 2005, in conjunction with a loan and security agreement, the Company issued warrants to purchase up to an aggregate of 97,668 shares of the Company's Common Stock at an exercise price of approximately \$4.10 per share. The warrants are exercisable through December 30, 2010. The Company determined the fair value of the warrants on the grant date, using the Black-Scholes pricing model, of \$241,000, which was recorded as a debt discount and is being amortized over 24 months, which is equal to the repayment term of the promissory note under the loan and security agreement. The assumptions used in determining the fair value of the warrants were a risk-free interest rate of 4.35%; dividend yield of 0%; expected volatility of 70%; and an expected life of five years. Amortization of approximately \$162,000 was recorded as interest expense during the year ended December 31, 2006, and for the period from January 21, 2000 (inception) to December 31, 2006, respectively. No interest expense was recorded during the year ended December 31, 2005. As of December 31, 2006, the warrants remained outstanding.

In March 2003, in conjunction with a loan and security agreement, the Company issued warrants to purchase shares of the Company's Series B Preferred Stock. Under the terms of the warrant agreement, upon the Company completing its IPO, the underlying preferred stock shares of the warrants converted into common stock shares. As a result, the underlying warrants were converted into warrants to purchase an aggregate of approximately 22,121 shares of the Company's Common Stock at an exercise price of approximately \$6.33 per share. The warrants are exercisable through March 20, 2010. The Company determined the fair value of the warrants on the grant date, using the Black-Scholes pricing model, of \$84,000, which was recorded as a debt discount and was amortized over the term of the loan and security agreement. The assumptions used in determining the fair value of the warrants were a risk-free interest rate of 3.0%; dividend yield of 0%; expected volatility of 70%; and an expected life of five years. Amortization of \$17,000 and \$84,000 was recorded as interest expense during the year ended December 31, 2005, and for the period from January 21, 2000 (inception) to December 31, 2006, respectively. No interest expense was recorded during the year ended December 31, 2006. As of December 31, 2006, the warrants remained outstanding.

In March 2001, in conjunction with its line of credit agreement, the Company issued a warrant to purchase shares of the Company's Series A Preferred Stock. On May 15, 2005, the warrant agreement was amended to allow the warrant holder to purchase up to an aggregate of 7,710 shares of the Company's Common Stock at an exercise price of approximately \$5.19 per share. The warrant is exercisable through the later of March 15, 2008 or five years after the Company's initial public offering. The Company determined the fair value of the warrant on the grant date, using the Black-Scholes pricing model, of \$22,400, which was recorded as a debt discount and was amortized over the term of the line of credit. The assumptions used in determining the fair value of the warrants were a risk-free interest rate of 4.3%; dividend yield of 0%; expected volatility of 60%; and an expected life of five years. Amortization of approximately \$500, \$4,900 and \$22,400 was recorded as interest expense during the years ended December 31, 2004 and 2003, and for the period from January 21, 2000 (inception) to December 31, 2006, respectively. As of December 31, 2006, the warrant remained outstanding.

The weighted-average exercise price of warrants outstanding as of December 31, 2006, 2005 and 2004 was approximately \$5.14, \$4.55 and \$5.02, respectively. The weighted-average fair value of warrants granted during 2006, 2005, 2004 and for the period from January 31, 2000 (inception) to December 31, 2006 was \$2.99, \$2.47, \$5.14 and \$2.98, respectively. The weighted-average remaining contractual life of the warrants outstanding at December 31, 2006 and 2005 was 4.26 years and 4.70 years, respectively.

#### ***Common Stock Reserved for Future Issuance***

The following shares of common stock were reserved for future issuance at December 31 (in thousands):

	<u>2006</u>	<u>2005</u>
Warrant for the purchase of common stock .....	3,372	127
Common stock options .....		
Granted and outstanding .....	2,365	1,682
Reserved for future issuance .....	632	380
Common stock reserved for Employee Stock Purchase Plan .....	229	273
	<u>6,598</u>	<u>2,462</u>

## 7. Income Taxes

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2006 and 2005 are shown below. A valuation allowance of \$53.1 million and \$36.7 million as of December 31, 2006 and 2005, respectively, has been recognized to offset the net deferred tax assets as realization of such net assets has not met "the more likely than not" threshold required under SFAS No. 109.

	December 31,	
	2006	2005
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 45,390	\$ 31,738
Tax credits .....	6,921	4,860
Deferred rent .....	1,126	538
Deferred compensation .....	300	262
Other .....	41	22
Total deferred tax assets .....	<u>53,778</u>	<u>37,420</u>
Valuation allowance for deferred tax assets .....	<u>(53,107)</u>	<u>(36,696)</u>
Net deferred tax assets .....	671	724
Deferred tax liabilities:		
Depreciation and amortization .....	(671)	(724)
Net deferred taxes .....	<u>\$ —</u>	<u>\$ —</u>

Reconciliation of the statutory federal income tax to the Company's effective tax:

	December 31,		
	2006	2005	2004
	(in thousands)		
Tax at federal statutory rate .....	\$ (14,179)	\$ (12,556)	\$ (9,113)
State, net of federal benefit .....	(2,049)	(1,836)	(1,327)
Tax credits .....	(2,061)	(2,355)	(800)
Change in valuation allowance .....	16,410	15,531	10,100
Permanent differences – Stock based compensation .....	1,403	1,001	883
Permanent differences – Other .....	496	589	242
Other .....	(20)	(374)	15
Provision for income taxes .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2006 and 2005, the Company had federal tax net operating loss carryforwards of approximately \$111.2 million and \$77.8 million, respectively. At December 31, 2006 and 2005, the Company had California tax net operating loss carryforwards of approximately \$112.6 million and \$78.5 million, respectively. The federal and California tax loss carryforwards will begin expiring in 2020 and 2012, respectively, unless previously utilized. At December 31, 2006, the Company also had federal and California research and development tax credit carryforwards totaling approximately \$4.8 million and \$3.1 million, respectively. The federal research and development tax credit carryforward will begin expiring in 2020 unless previously utilized. At December 31, 2006, the Company had a California manufacturer's investment credit carryforward of approximately \$141,000.

Internal Revenue Code § 382 and § 383 limit the availability of income tax net operating losses and tax credit carryforwards that arise prior to certain cumulative changes in a corporation's ownership resulting in change of control of the Company should such changes in ownership occur. Pursuant to Internal Revenue Code § 382 and § 383, use of the Company's net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

## 8. Related Party Transactions

In July 2004 and July 2005, the Company entered into consulting agreements with a family member of one of its executive officers (the Consultant) to provide agreed upon services to the Company and receive compensation based upon an hourly rate. The term of the consulting agreements were one year but the agreements automatically renewed in one year increments unless otherwise terminated by the parties. The Consultant is no longer providing services under the July 2004

agreement. The July 2005 agreement was terminated in March 2006. For the years ended December 31, 2006, 2005 and 2004, and the period from January 21, 2000 (inception) to December 31, 2006, the Company paid the Consultant approximately \$46,000, \$75,000, 19,000 and \$140,000, respectively, including reimbursement of ordinary business expenses.

In March 2003, the Company entered into a consulting agreement with one of its major investors (the Investor). The Investor designated a consultant to provide certain administrative, business and technical support to the Company. Compensation under the agreement included a fee of \$8,500 per month to be paid to the Investor for performance of services provided by the consultant. In addition, a warrant for the purchase of up to 19,277 shares of the Company's Common Stock was issued to the consultant (Note 5). The agreement terminated in 2005. For the years ended December 31, 2005 and 2004, and the period from January 21, 2000 (inception) to December 31, 2006, the Company paid the Investor approximately \$70,000, \$150,000 and \$313,000 respectively, including reimbursement of ordinary business expenses.

In February 2001, April 2003 and April 2005, the Company entered into consulting agreements with one of its directors (the Director). Under the terms of the consulting agreements the Director would provide agreed upon services to the Company and receive compensation based upon an hourly rate. The initial term of the consulting agreements are one year but the agreements automatically renew in one year increments unless otherwise terminated by the parties. The Director ceased providing services under the February 2001, April 2003 and April 2005 agreements. For the years ended December 31, 2005 and 2004, and the period from January 21, 2000 (inception) to December 31, 2006, the Director received compensation of approximately \$6,000 and \$7,000 and \$61,000, respectively.

In September 2000, the Company entered into a lease agreement with a non-profit organization with which the Company shares a common director. The related rent expense was \$124,000, \$476,000 and \$1.6 million for the years ended December 31, 2004, 2003 and for the period from January 21, 2000 (inception) to December 31, 2006, respectively. The lease agreement expired on March 31, 2004.

## 9. Subsequent Events

On February 12, 2007, the Company entered into common stock purchase agreements with certain investors relating to a registered direct offering of an aggregate 3,333,334 shares of the Company's common stock at \$3.00 per share to the investors for gross proceeds of approximately \$10 million.

The common stock was issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 13, 2007, in connection with a shelf takedown from the Company's Registration Statement on Form S-3 (File No. 333-135169) which became effective on July 11, 2006.

## 10. Quarterly Financial Data (unaudited)

The following table summarizes certain of the Company's operating results by quarter for 2006 and 2005 (in thousands):

	2006				
	First	Second	Third	Fourth	Total
Net loss applicable to common stockholders (a): . . . . .	\$ (10,855)	\$ (9,825)	\$ (9,585)	\$ (10,248)	\$ (40,511)
Net loss per share applicable to common stockholders (a): . . . . .	\$ (0.49)	\$ (0.34)	\$ (0.339)	\$ (0.35)	\$ (1.49)
	2005				
	First	Second	Third	Fourth	Total
Net loss applicable to common stockholders (a): . . . . .	\$ (8,411)	\$ (9,373)	\$ (8,524)	\$ (9,573)	\$ (35,881)
Net loss per share applicable to common stockholders (a): . . . . .	\$ (0.69)	\$ (0.47)	\$ (0.43)	\$ (0.48)	\$ (1.99)

(a) The sum of the four quarters will not agree to the year total due to rounding within a quarter.

## Index to Exhibits

15. (b) The following exhibits are filed as part of, or incorporated into, the 2006 Favril, Inc. Annual Report on Form 10-K:

Exhibit Number	Description of Document
3.1	Registrant's Amended and Restated Certificate of Incorporation.(1)
3.2	Registrant's Amended and Restated Bylaws.(1)
4.1	Form of Common Stock Certificate of Registrant.(1)
4.2	Amended and Restated Investor Rights Agreement dated March 26, 2004 between the Registrant and certain of its stockholders.(1)
4.3	Amendment No. 1 to Amended and Restated Investor Rights Agreement dated April 6, 2004 between the Registrant and certain of its stockholders.(1)
4.4	Securities Purchase Agreement dated March 6, 2006, by and among Favril and the individuals and entities identified on Exhibit A thereto (the "Securities Purchase Agreement").(7)
4.5	Registration Rights Agreement, dated December 19, 2006, by and between Favril and Kingsbridge Capital Limited.(9)
4.6	Securities Purchase Agreement dated February 12, 2007, by and among Favril and certain investors.(10)
4.7	Warrant to purchase 250,000 shares of Common Stock dated December 19, 2006 issued to Kingsbridge Capital Limited.(9)
4.8	Form of Warrant issued pursuant to the Securities Purchase Agreement.(7)
4.9	Warrant to purchase 48,834 shares of Common Stock dated December 30, 2005 issued to General Electric Capital Corporation.(6)
4.10	Warrant to purchase 48,834 shares of Common Stock dated December 30, 2005 issued to Oxford Finance Corporation.(6)
10.1	Form of Indemnity Agreement for Registrant's directors and officers.(1)(2)
10.2	Form of Indemnity Agreement for Registrant's directors and officers.(8)(2)
10.3	Amended and Restated 2001 Equity Incentive Plan and Form of Stock Option Agreement thereunder.(1)(2)
10.4A	2005 Non-Employee Directors' Stock Option Plan, as amended (the "NEDSOP").(2)
10.4B	Form of Stock Option Agreement under the NEDSOP.(1)(2)
10.5	2005 Employee Stock Purchase Plan and Form of Offering Document thereunder.(1)(2)
10.6	Employment Agreement dated January 6, 2005 between the Registrant and John P. Longenecker, Ph.D.(1)(2)
10.7	Office Lease dated January 31, 2003 between the Registrant and Kilroy Realty, L.P.(1)
10.8	First Amendment to Lease dated July 7, 2004 between the Registrant and Kilroy Realty, L.P.(1)
10.9	Master Security Agreement dated July 26, 2004 between the Registrant and Oxford Finance Corporation.(1)
10.10	Loan and Security Agreement No. 24-0117 dated March 20, 2003 among the Registrant, Heller Financial Leasing, Inc. and Lighthouse Capital Partners IV, L.P.(1)
10.11	Supply Agreement made on November 12, 2004 between the Registrant and Biosyn Arzneimittel GmbH.(1)(3)
10.12	Employment Agreement dated January 6, 2005 between the Registrant and Tamara A. Seymour.(1)(2)
10.13	Employment Agreement dated January 6, 2005 between the Registrant and Daniel P. Gold, Ph.D.(1)(2)
10.14	Employment Agreement dated January 6, 2005 between the Registrant and Alice Wei.(1)(2)
10.15	Employment Agreement dated January 6, 2005 between the Registrant and John F. Bender, Pharm.D.(1)(2)
10.16	Employment Agreement dated January 6, 2005 between the Registrant and Richard Murawski.(1)(2)
10.17	Employment Agreement dated December 1, 2005 between the Registrant and David L. Guy.(2)(6)
10.18	Form of Employment Agreement between the Registrant and its executive officers.(1)(2)
10.19	Letter Agreement dated May 28, 2004 between the Registrant and Oxford Finance Corporation.(4)
10.20	Amendment dated June 16, 2005 to the Master Security Agreement dated July 26, 2004 between the Registrant and Oxford Finance Corporation.(4)
10.21	Letter Agreement dated June 27, 2005 between the Registrant and Oxford Finance Corporation.(4)
10.22	Third Amendment to Lease dated July 7, 2005 between Registrant and Kilroy, L.P.(4)
10.23	Amended and Restated Office Lease dated October 31, 2005 between the Registrant and Kilroy Realty, L.P.(5)
10.24	Master Security Agreement dated December 30, 2005 between the Registrant and General Electric Capital Corporation.(6)
10.25	Amendment dated December 30, 2005 to the Master Security Agreement dated December 30, 2005 between the Registrant and General Electric Capital Corporation.(6)
10.26	Promissory Note dated December 30, 2005 between the Registrant and General Electric Capital Corporation.(6)

- 10.27 Amendment dated December 30, 2005 to the Master Security Agreement dated July 26, 2004 between the Registrant and Oxford Finance Corporation.(6)
- 10.28 Promissory Note dated December 30, 2005 between the Registrant and Oxford Finance Corporation.(6)
- 10.29 Common Stock Purchase Agreement dated December 19, 2006 between the Registrant and Kingsbridge.(9)
- 23.1 Consent of Independent Registered Public Accounting Firm.
- 24.1 Power of Attorney. Reference is made to the signature page of this report.
- 31.1 Certification of principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
- 31.2 Certification of principal accounting officer required by Rule 13a-14(a) or Rule 15d-14(a).
- 32 Certification by the Chief Executive Officer and Chief Financial Officer of Faville, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.1350).

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- (1) Previously filed as an Exhibit to Faville, Inc.'s Registration Statement on Form S-1 (No. 333-114299), as amended (the "Registration Statement"), and incorporated by reference herein.
  - (2) Indicates management contract or compensatory plan.
  - (3) Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
  - (4) Filed on August 12, 2005 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated herein by reference.
  - (5) Filed on November 14, 2005 as an exhibit to the Company's Quarterly Report on Form 10-Q and incorporated herein by reference.
  - (6) Filed on March 29, 2006 as an exhibit to the Company's Annual Report on Form 10-K and incorporated herein by reference.
  - (7) Filed as an exhibit to the Company's Current Report on Form 8-K dated March 6, 2006 and incorporated herein by reference.
  - (8) Filed as an exhibit to the Company's Current Report on Form 8-K dated December 7, 2006 and incorporated herein by reference.
  - (9) Filed as an exhibit to the Company's Current Report on Form 8-K dated December 20, 2006 and incorporated herein by reference.
  - (10) Filed as an exhibit to the Company's Current Report on Form 8-K dated February 13, 2007 and incorporated herein by reference.



/s/ WAYNE I. ROE  
Wayne I. Roe

Director

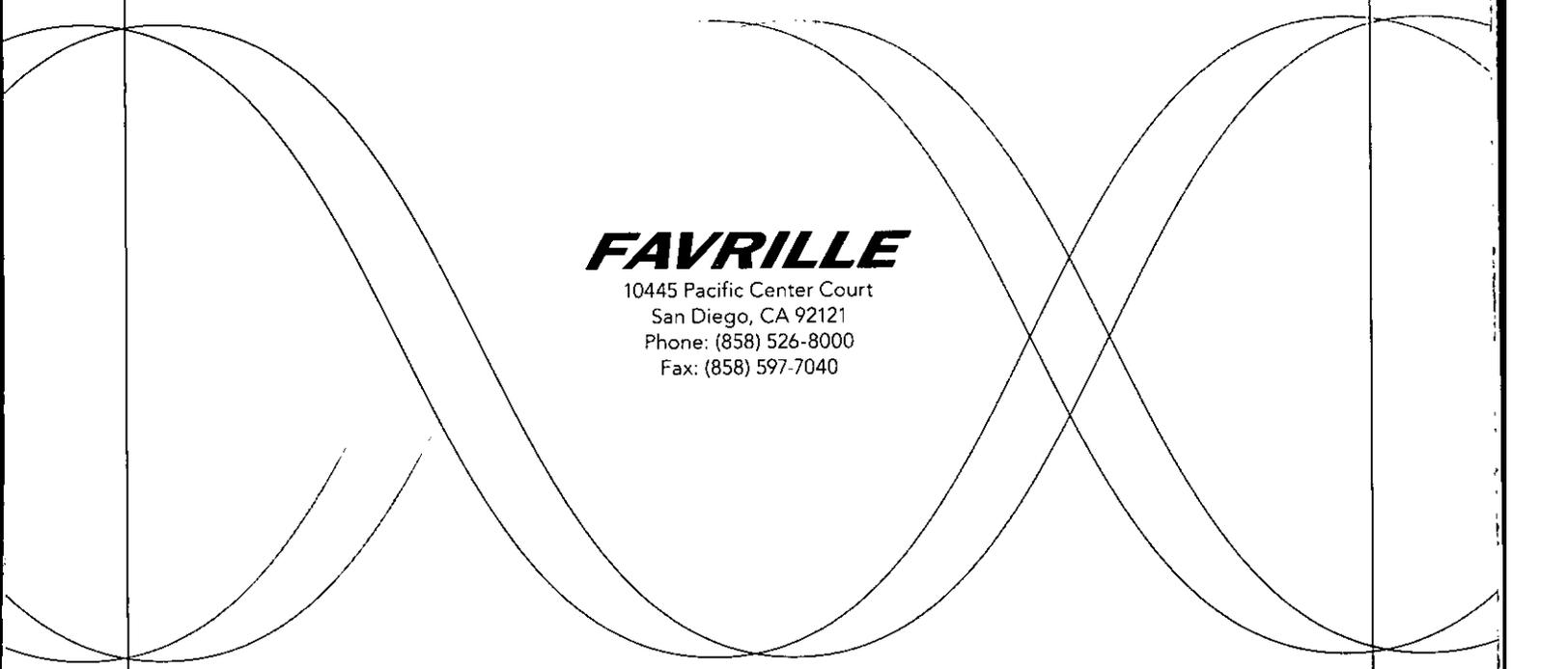
March 28, 2007

Ivor Royston, M.D.

Director

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***FAVRILLE***

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