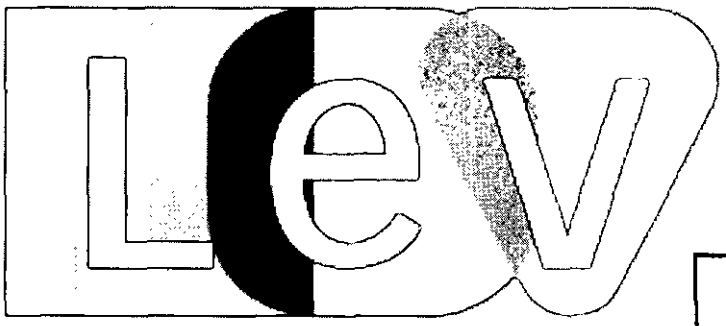


2007 Annual Report

Letter to Shareholders

Dear Fellow Shareholders:

Last year represented a year of solid progress for our company. We achieved many milestones during 2007 in advancing our lead product candidate, Cinryze™ (C1 inhibitor), as a replacement therapy for the treatment of hereditary angioedema (HAE) or C1 inhibitor deficiency. Our achievements reflect Lev's ongoing commitment to providing relief for patients with this rare, debilitating and life-threatening genetic disorder.

Our clinical development efforts have provided a strong foundation for creating value. In March 2007, we announced the successful completion of our pivotal Phase III clinical trial of Cinryze™ for the acute treatment of HAE, achieving our primary endpoint, which demonstrated a clinically and statistically significant reduction in the time to unequivocal relief of acute HAE attacks. In September, we reported positive results from our pivotal U.S. Phase III trial of Cinryze™ for the prophylactic treatment of HAE. In the study, the protocol-defined, pre-specified primary endpoint was achieved, showing a clinically and statistically significant reduction in the number of HAE attacks.

On the regulatory front, we submitted our Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in July seeking approval of Cinryze™ for the acute treatment of HAE. Our prophylactic data were submitted in October as an amendment to the BLA. FDA accepted our BLA filing for Cinryze™ and designated the submission for priority review.

On January 30, 2008 we received a complete response letter from FDA, also known as an "approvable letter." A complete response letter is issued by FDA to request additional information in connection with its review. In its letter, FDA requested information with respect to chemistry, manufacturing, and controls (CMC), as well as additional analyses of existing efficacy data from the Cinryze™ trials. Presently, we are preparing to formally submit our responses to FDA's letter. Notably, no additional safety information and no additional clinical trials have been requested to date.

We are also diligently preparing for our presentation to FDA's Blood Products Advisory Committee (BPAC) scheduled for May 2, 2008. Advisory committees provide FDA with independent advice from outside experts. The BPAC meeting represents the next stage in the regulatory process for Cinrzye™. We are pleased to have the opportunity to present our data to the panel of independent experts and view this as an important step toward securing approval of Cinryze™.

While we have been working through the regulatory process with FDA, we are continuing to provide patients with access to Cinryze™ through Lev's First Dose program with more than 100 qualified HAE patients enrolled in our ongoing open-label acute and prophylactic trials. To date, more than 6,000 doses of Cinryze™ have been administered in all parts of our CHANGE (*C1inhibitor in Hereditary Angioedema Nanofiltration Generation evaluating Efficacy)* trials with more than a dozen patients having individually received well over 100 doses.

Through our market research, ongoing clinical trials, and other initiatives, we have developed a target list of approximately 700 HAE-treating allergists in the U.S. with 175 of these doctors treating approximately 70% of the diagnosed patient population in the U.S. Importantly, the size of the HAE prophylactic market continues to grow as we've identified 1,000 to 1,500 HAE

patients that are currently using anabolic steroids prophylactically to manage their disease – currently the most widely available prophylactic treatment option in the U.S.

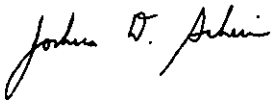
Anabolic steroids, however, are associated with dangerous toxicities and side effects, and are contraindicated for a large segment of the population, most notably women and children. The patients who take anabolic steroids today serve as a strong proxy for the size of the potential HAE prophylactic market for Cinrzye™. Our market research indicates a high percentage of the most significantly affected HAE patients are motivated to convert to prophylactic treatment with Cinryze™. Upon approval, we believe Cinryze™ will be an important option both for patients who are currently taking steroids, as well as those patients for whom steroids are not appropriate or tolerable.

In parallel to our regulatory advances for the approval of Cinryze™, we are preparing for a commercial launch. We have assembled an experienced and dynamic commercial management team with strong pharmaceutical experience and a successful track record in launching major new products. We are working to complement our current marketing and operational expertise by developing an internal orphan drug sales organization. We currently expect to have a group of roughly 9-12 sales representatives in the U.S.; however, we will continue to refine our analysis going forward to determine the most productive size and distribution of this sales force. We also made important progress in developing and cementing our brand in 2007, receiving approval from FDA to use our brand name Cinryze™.

Throughout the course of the year, we worked to raise the awareness of HAE as an unmet medical need and highlighting the value of C1 inhibitor replacement therapy – a treatment option that has been available in Europe for more than 35 years, but has never before been approved for HAE patients in the U.S. Through our scientific and medical communications programs, we have been developing valuable relationships with experts in allergy and immunology to further expand the awareness of HAE and to develop a broad understanding of issues related to symptoms, diagnosis, and patient outcomes.

In continuing our commitment to serving these critically ill patients, Lev is establishing a patient access program to support HAE patients and their caregivers. Our efforts within the HAE community give us insight into their needs and provide a conduit through which patients, physicians, caregivers, and advocates can share valuable insights and experiences.

Looking forward, we are well positioned to deliver value to our key stakeholders: patients, physicians, caregivers, shareholders and employees. We are excited about the many opportunities and challenges that lie ahead as we work with FDA toward obtaining approval of Cinryze™ to improve the lives of patients and families who suffer from C1 inhibitor deficiency.



Joshua D. Schein, Ph.D.
Chief Executive Officer

Judson Cooper
Chairman of the Board

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

FORM 10-K

(Mark One)

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

For The Fiscal Year Ended December 31, 2007

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

COMMISSION FILE NO. **000-32947**

LEV PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**88-0211496**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

675 Third Avenue, Suite 2200, New York, New York 10017
(Address of principal executive offices and zip code)

(212) 682-3096
(Issuer's Telephone Number, Including Area Code)

SECURITIES REGISTERED UNDER SECTION 12(b) OF THE EXCHANGE ACT: **NONE**

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE EXCHANGE ACT: **Common Stock, $.01 Par Value Per Share**

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 Exchange 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 Exchange Act 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 ☐ Smaller reporting company ☐

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

The aggregate market value of the voting common stock held by nonaffiliates of the registrant as of June 30, 2007 was approximately $96,160,848.

The number of shares of the registrant's common stock outstanding as of March 1, 2008: 142,329,157 shares.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (e) under the Securities Act of 1933.

Part III of this report incorporates information by reference from the Company's definitive proxy statement, which proxy statement is due to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2007.

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PART I

ITEM 1. DESCRIPTION OF BUSINESS

Some of the statements contained in this annual report are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. We and our representatives may from time to time make written or oral statements that are "forward-looking," including statements contained in this Form 10-K and other filings with the Securities and Exchange Commission, reports to our stockholders and news releases. All statements that express expectations, estimates, forecasts or projections are forward-looking statements within the meaning of the Act. In addition, other written or oral statements which constitute forward-looking statements may be made by us or on our behalf. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in or suggested by such forward-looking statements. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Among the important factors on which such statements are based are:

- *assumptions concerning uncertainties associated with product development;*
- *risks related to new information arising out of clinical trial results;*
- *the risk that the safety and/or efficacy results of existing clinical trials for Cinryze™ will not support approval for a biologics license;*
- *the risk that the FDA may require us to conduct additional clinical trials for Cinryze™;*
- *the risk that the FDA may interpret data differently than we do or require more data or a more rigorous analysis of data than expected;*
- *the risk that we will not obtain regulatory approval to market our products;*
- *the risk that our products will not gain market acceptance;*
- *our ability to obtain additional financing;*
- *our ability to attract and retain key employees;*
- *our heavy dependence on the success of Cinryze™;*
- *our dependence on our suppliers and third parties to manufacture Cinryze™;*
- *maintaining the orphan drug status associated with Cinryze™;*
- *the risks associated with dependence upon key personnel;*
- *our ability to protect intellectual property; and*
- *our ability to adapt to economic, political and regulatory conditions affecting the healthcare industry.*

All references to "we," "our," "us," "Lev" and the "Company" in this Annual Report on Form 10-K refer to Lev Pharmaceuticals, Inc. and its wholly-owned subsidiary, Lev Development Corp.

Introduction

We are a development stage biopharmaceutical company that was formed in July 2003 to develop and commercialize therapeutic products for the treatment of inflammatory diseases. Our product candidates are based on C1-esterase inhibitor, C1-INH, a human plasma protein that modulates inflammation and is potentially applicable as a treatment for a range of medical indications. During 2005, we initiated a Phase III clinical trial of our lead product candidate, C1-INH for the treatment, both acute and prophylactic, of hereditary angioedema ("HAE"). In October 2005, we received fast track designation status by the U.S Food and Drug Administration, ("FDA") for the treatment of HAE.

On March 14, 2007, we announced positive results from our Phase III clinical trial of C1-INH for the acute treatment of HAE and based on the positive results of this trial, we filed a biologics license application, or BLA, with the FDA on July 31, 2007. The FDA accepted our BLA for filing on October 1, 2007 and designated our submission for priority review. In addition, on September 10, 2007 we announced positive results from our Phase III clinical trial of C1-INH for the prophylactic treatment of HAE and based on the positive results of this study, we amended our BLA filing with the FDA on October 30, 2007. On January 30, 2008, we announced our receipt of a complete response letter from the FDA

regarding our BLA for Cinryze™ for the acute and prophylactic treatment of Hereditary Angioedema. In our announcement, we stated that the FDA requested information with respect to chemistry, manufacturing and controls, as well as additional analyses of existing efficacy data from the Cinryze™ trials. While no new clinical trials were requested in this letter, no assurances can be given that additional clinical studies will not be requested in the future or on the timing of any further FDA action. We are in the process of compiling our response to the information requested by the FDA. In addition, we have been advised that the U.S. Food and Drug Administration's Blood Products Advisory Committee, or BPAC, intends to review our BLA for Cinryze on May 2, 2008, for the prophylactic treatment of HAE. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the BLA. Accordingly, there can be no assurance that the FDA will ultimately approve our BLA. If approved, we intend to commercialize Cinryze™ through a specialty sales force in the United States.

We are also developing C1-INH for the treatment of selective other diseases and disorders, such as acute myocardial infarction ("AMI"), or heart attack, in which inflammation is known or believed to play an underlying role. We have certain rights to C1-INH technology through agreements with Sanquin Blood Supply Foundation ("Sanquin"), an Amsterdam-based not-for-profit organization that provides blood and plasma products and related services, carries out research and provides education, primarily in the Netherlands.

Corporate History

Public Company Merger

On November 5, 2004, Fun City Popcorn, Inc. a non-operating public company incorporated in Nevada ("FCP"), Lev Acquisition Corp., its wholly-owed subsidiary ("Lev Sub"), and Lev Development Corp., previously know as Lev Pharmaceuticals, Inc. ("Old Lev" or "LDC"), entered into an Agreement and Plan of Merger (as amended on December 8, 2004, the "Agreement"). On December 29, 2004, the merger closed and pursuant to the Agreement, Lev Sub merged into Old Lev and the combined entity became a wholly-owned subsidiary of FCP (the "Public Company Merger"). As a result of the Public Company Merger, FCP issued 5,029,795 shares of common stock and 4,789,433 shares of Series A convertible preferred stock to holders of outstanding Old Lev common stock.

Delaware Reincorporation

Later, on December 29, 2004, the Board of Directors and stockholders of FCP approved a merger of FCP into a newly formed, wholly-owned subsidiary of FCP incorporated in Delaware (the "Recapitalization Merger"). This merger was undertaken to increase the authorized number of shares of common stock to permit the conversion of the Series A preferred stock, to reincorporate FCP in the State of Delaware and to change the name of the company. On February 17, 2005, the Recapitalization Merger closed and the issued and outstanding Series A Preferred Stock of FCP was automatically converted into an aggregate of 66,767,994 shares of common stock, which, along with the 4,505,530 shares of FCP common stock outstanding prior to the Public Company Merger and the 5,029,795 shares of common stock issued to the Old Lev stockholders in the Public Company Merger, resulted in a total of 76,303,319 shares of common stock outstanding as of February 17, 2005. As part of the Recapitalization Merger, Old Lev changed its name to Lev Development Corp. and FCP changed its name to Lev Pharmaceuticals, Inc. As a result of these mergers, the stockholders of Old Lev acquired approximately 94% of our outstanding common stock.

Product Programs

Hereditary Angioedema (HAE)

Our lead program is the development of C1-INH for the treatment of HAE. HAE is a rare genetic disorder characterized by episodic attacks of edema (swelling) in the extremities, face, abdomen, and most seriously, the airway passages. The disease is caused by a deficiency of C1-INH, and there are believed to be 10,000 or more people with HAE in the United States. In July 2004, we received orphan drug designation from the FDA for C1-INH (human), which, upon product licensure from the FDA, could provide us with a seven-year exclusive right to market the C1-INH product as a treatment for HAE in the United States. This designation is for both acute and prophylactic treatment. In October 2005, we received fast track designation status by the FDA for both acute and prophylactic treatment of HAE. Fast track designation facilitates the development and expedites the review of drugs and biologics intended to treat serious or life-threatening

conditions that demonstrate the potential to address unmet medical needs. We initiated a Phase III clinical trial of C1-INH for the acute treatment of HAE in March 2005 and in November 2005 we initiated a Phase III clinical trial of C1-INH for the prophylactic treatment of HAE. A detailed discussion of the material developments regarding the regulatory pathway for this product candidate is contained below under the caption "*C1-Esterase Inhibitor (C1-INH) for the Treatment of HAE*".

Other Product Programs

Our second development program is focused on the use of C1-INH in treating AMI, commonly known as a heart attack. AMI results from an obstruction of blood flow to the heart. There are approximately 865,000 patients with AMI in the United States annually, resulting in an estimated 171,000 directly attributable deaths. Current treatments for AMI, both surgical and pharmaceutical, are directed at restoring blood flow to heart tissue or preventing further obstruction. Despite a widespread appreciation for the role of inflammation in AMI in both the scientific and medical communities, no presently available treatments directly target the mechanisms of inflammation. Based on preliminary animal and clinical data presented by others, we believe that C1-INH may be useful as a treatment for AMI. We may initiate a research program in 2008 for the development of a genetically engineered or recombinant version of C1-INH to be used in the treatment of AMI. In 2008, we may also initiate studies for C1-INH in treating AMI. There can be no assurance, however, that we will have sufficient resources to deploy in furtherance of all of these potential research programs, in addition to our ongoing clinical trials, within the next twelve months or at all.

The process of inflammation underlies a number of other serious diseases, including gram-negative septicemia and inflammatory bowel disease, and is now also understood to play a role in other disorders previously thought to be unrelated to inflammation, including Alzheimer's disease and stroke. As a potent mediator of inflammation, C1-INH has been examined as a potential treatment for some of these diseases in animal studies, and, in a limited number of disorders, in clinical studies as well. Based on these studies, and on the role C1-INH is known to play in inhibiting key inflammatory pathways, we intend to develop C1-INH for certain other diseases and disorders. We believe that the extensive clinical experience with C1-INH in treating HAE in Europe will facilitate its introduction into other clinical indications.

Strategy

Our goal is to create a biopharmaceutical company that develops and commercializes a portfolio of C1-INH products that offer improved efficacy and safety characteristics over existing treatments. The key elements of our strategy are to:

- complete the development of our lead product candidate, C1-INH for the treatment of HAE;
- market and sell our HAE product independently or together with a third party;
- advance our second product candidate, C1-INH for the treatment of AMI, into early-stage clinical development in the United States; and
- selectively develop C1-INH for additional therapeutic indications.

Technology

C1-INH is a human plasma protein that mediates inflammation and coagulation. In Europe, C1-INH, produced by several manufacturers, has been used to treat patients with HAE safely and effectively for more than 30 years, and is widely accepted as the treatment of choice for HAE. It is this extensive record of safety and efficacy that provides the basis for our lead program, the development of C1-INH in the United States for the treatment of HAE.

Beyond this record of clinical experience, however, C1-INH is also a well-characterized and well-understood molecule that is known to play a key role regulating the complex biochemical interactions of blood-based systems involved in inflammation and coagulation. C1-INH is known to be either a major or minor inhibitor of multiple proteins involved in these systems. More specifically, C1-INH is known to inhibit three key biochemical pathways underlying inflammation and/or coagulation - the complement system, the contact pathway of intrinsic coagulation and the fibrinolytic system. Under normal circumstances, these systems play important roles in defending the body from infection, injury and disease and in repairing tissue damage. If improperly controlled, however, these same systems can cause or contribute to disease and tissue damage. Excessive activity in one or more of these systems is known or believed to contribute to a number of diseases or disorders, including: myocardial infarction, ischemic-reperfusion injury, inflammatory bowel disease, gram-

negative septicemia, Alzheimer's disease and stroke.

Based on (i) the demonstrated role of these inflammatory pathways in specific diseases, (ii) the known function of C1-INH in regulating these pathways and (iii) the extensive clinical experience in using C1-INH to treat HAE, C1-INH has been extensively studied, both clinically and pre-clinically, as a potential treatment for a number of diseases. We intend to leverage and extend these studies to develop a portfolio of products based on C1-INH.

Hereditary Angioedema (HAE)

Background

HAE is a genetic disorder characterized by episodes of edema (swelling) in the extremities, face, abdomen, and airway passages. The majority of patients have stretches of severe abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Attacks that involve the face and throat must be taken seriously and medical treatment should be sought without delay. Swelling of the throat can close the air passage and cause death by suffocation. The mortality rate from untreated airway obstruction has been reported to be over 30% with death most frequently caused by asphyxiation due to airway closure. The course of the disease is diverse and unpredictable, even within a single patient over his lifetime. Swelling caused by HAE usually lasts for 24-72 hours, but the length of an attack can range from four hours to four days. On average, patients experience approximately one attack per month, but the frequency is highly variable. As many as 5% to 10% of patients are severely affected, experiencing attacks one to three times per week. HAE affects between 1:10,000 and 1:50,000 individuals worldwide and there are believed to be 10,000 or more people with HAE in the United States.

HAE is caused by a defective gene for C1-INH, and this defect is passed on in families - a child has a 50% chance of inheriting this disease if one parent is affected. The absence of family history, however, does not rule out HAE diagnosis, and as many as 20% of HAE cases involve patients who appear to have had a spontaneous mutation of the C1-INH gene at conception. The genetic defect results in production of either inadequate or nonfunctioning C1-INH protein.

C1-INH is known to inhibit three key biochemical pathways underlying inflammation and/or coagulation - the complement system, the contact pathway of intrinsic coagulation and the fibrinolytic system. Excessive activity of each of these systems has been demonstrated in HAE, as evidenced by increased levels of components of the complement system, kallikrein, coagulation Factors XIa and XIIa, and plasmin. The biochemical imbalance that results from reduced levels of functional C1-INH leads to the production of proteins and peptides that cause fluids to be released from the capillaries into surrounding tissues thereby causing edema.

In the absence of C1-INH activity, activated C1 and plasmin generate certain inflammatory mediators that are thought to be causal factors of the angioedema observed in patients with HAE. C1-INH concentrate replaces the missing or non-functional protein and inhibits the catalytic subunits of the first component of the classic complement pathway (C1r and C1s), and also inhibits the function of kallikrein, plasmin, and coagulation factors XIa and XIIa.

Because HAE is rare and has a wide variability in disease expression, it is not uncommon for patients to remain undiagnosed or misdiagnosed for many years. Many patients report that their frequent and severe abdominal pain was inappropriately diagnosed as psychosomatic. Although rare, HAE is a disease with potentially catastrophic consequences for those affected. Aside from the potentially fatal acute respiratory compromise, unnecessary exploratory surgery has been performed on patients experiencing gastrointestinal edema because abdominal HAE attacks mimic conditions requiring surgery.

Traditionally, HAE has been classified into two types (I and II). The most common form of the disease, Type I, is characterized by low levels of C1-INH and affects about 85% of patients, whereas Type II HAE affects 15% of patients and is characterized by non-functional C1-INH. A third type of HAE has been identified in which the abnormal C1-INH protein binds to albumin, effectively reducing the amount of functional C1-INH.

Current Treatments of HAE

Treatment of HAE can be categorized as: (i) mitigation or acute treatments to remedy the symptoms of infrequent episodic acute attacks; and (ii) preventive or prophylactic treatments for patients severely affected by HAE.

There are currently no approved treatments for acute attacks available in the United States. Rather, current therapies primarily focus upon treating the symptoms of an acute attack. For swelling of the intestinal wall, which can cause debilitating pain, narcotics such as morphine and antiemetics for nausea are given, but these medications only address the symptoms and not the underlying cause. For severe laryngeal swelling, which can be life threatening, rescue therapy such as intubation or tracheotomy may be required. The use of fresh frozen plasma, which contains C1-INH but which also contains a wide variety of other factors that may activate multiple inflammatory pathways and exacerbate an attack, is also used in some instances. Facial and extremity attacks are usually left to resolve on their own.

Long-term prevention therapy is recommended for patients who experience more than one attack per month, or for whom the disease significantly interferes with their quality of life. Most of these patients are currently treated with anabolic steroids that reduce the frequency of attacks of edema. The most commonly used steroids are alpha-alkylated androgens such as stanozolol and danazol. Although these drugs are effective in some patients in reducing the number and severity of the most serious attacks, they do not prevent all attacks. In addition, use of such anabolic steroids can have numerous side effects ranging from hepatotoxicity (liver toxicity), virilization (development of male sexual characteristics in a female), weight gain, acne and hirsutism (unwanted hair growth).

C1-Esterase Inhibitor (C1-INH) for the Treatment of HAE

HAE has been shown to be effectively treated with intravenous administration of C1-INH purified from human plasma. In Europe, C1-INH, produced by several manufacturers, has been used to treat patients with HAE safely and effectively for more than 30 years, and is widely accepted by treating physicians and HAE associations around the world as the treatment of choice for acute attacks of HAE. It can be used to treat acutely, when there is an attack, or prophylactically, to prevent attacks. This treatment concept is similar to hemophilia, in which a patient is treated regularly with the particular clotting factor for which he is deficient, as well as on demand for specific bleeding episodes. In spite of this long record of safety and efficacy in Europe, C1-INH has never been introduced in the United States, and it is our objective to bring C1-INH to the United States for the treatment of patients with HAE.

Our first product candidate, C1-INH prepared from human plasma, is being developed for both acute and prophylactic treatment of HAE. C1-INH is given by intravenous administration. Published studies by others have shown C1-INH treatment to resolve angioedema in 30 minutes to two hours, compared to 24-72 hours when untreated. A research study published in the New England Journal of Medicine in 1996 provided evidence that this treatment was safe and effective for both prevention of attacks and as an acute attack therapy. In addition, rapid resolution of laryngeal, facial, abdominal, and extremity swelling was observed. A study published in the Archives of Internal Medicine in 2001 concluded C1-INH to be highly effective in treating the laryngeal edema of HAE with rapid resolution of symptoms. We believe these studies, which did not involve our product, and others showing comparable efficacy, are representative of the extensive European clinical experience using C1-INH as a treatment for HAE for more than 30 years.

On March 2, 2005, we entered into a CRO (Clinical Research Organization) services agreement with INC Research which governs INC Research's provision of services in connection with the support of clinical investigation, management and/or research of our Phase III clinical trial. We entered into a separate services agreement with INC Research in September 2006 which governs INC Research's provision of additional services in connection with our Phase III clinical trials and activities related to the commercialization of our product candidates. The services provided by INC Research pursuant to both contractual arrangements are on a work-order basis and we are invoiced on a time and materials basis. We have the right to terminate both agreements, and any pending work-order, on prior notice and without cause. As of December 31, 2007, we have estimated that we will pay INC Research at least $567,000 for its services under both agreements in 2008. However, due to the variability associated with the conduct of clinical trials, we are unable to estimate with certainty the future costs we will incur under our CRO agreement.

In July 2004, we received orphan drug designation from the FDA for C1-INH (human), which, upon product licensure from the FDA, could provide us with a seven-year exclusive right to market the C1-INH product as a treatment for HAE in the United States. This designation is for both acute and prophylactic treatment. In October 2005, we received fast track designation status by the FDA for both acute and prophylactic treatment of HAE. Fast track designation facilitates the development and expedites the review of drugs and biologics intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. We initiated a Phase III clinical trial of C1-INH for the acute treatment of HAE in March 2005. In November 2005, we initiated a Phase III clinical trial of C1-INH for the prophylactic

treatment of HAE. The trials were multi-center, placebo-controlled, double-blind studies designed to examine the use of C1-INH in both treating acute attacks of HAE and in preventing the onset of such attacks. Phase III clinical trials of this type are highly unpredictable, and may take from one year to many years for completion, depending on a large number of factors, most of which were entirely beyond our control.

On January 17, 2007, we announced that we have completed patient treatment in the acute portion of a pivotal Phase III clinical trial for our lead product candidate, C1-INH for the treatment of HAE and on March 14, 2007, we announced positive results from our Phase III clinical trial of C1-INH for the acute treatment of HAE. In the acute trial, the protocol-defined primary endpoint was reached, showing a clinically and statistically significant reduction in the time to sustained relief of acute HAE symptoms. The primary endpoint was met using the protocol-defined intent to treat analysis, with a median time to sustained symptom relief of 2.0 hours for patients receiving C1-INH compared to greater than 4.0 hours, the maximum evaluation period, for patients receiving placebo. In addition, 21 laryngeal attacks were treated in the study on an open label basis. All of the laryngeal attacks were successfully treated with C1-INH. Based on the positive results of this trial, we filed a biologics license application, or BLA, with the FDA on July 31, 2007. The FDA accepted our BLA for filing on October 1, 2007 and designated our submission for priority review.

On May 31, 2007, we announced that we have completed patient treatment in the second phase of the trial, examining the effectiveness of C1-INH in preventing inflammatory attacks in more severely affected HAE patients and on September 10, 2007 we announced positive results from our Phase III clinical trial of C1-INH for the prophylactic treatment of HAE. In the prophylactic trial, the protocol-defined primary endpoint was achieved, showing a clinically and statistically significant reduction in the number of HAE attacks. In the 24 week, double-blind, placebo controlled study, a total of 24 patients were randomly assigned to one of two treatment groups: twelve weeks of C1-INH treatment followed by 12 weeks of placebo or 12 weeks of placebo treatment followed by 12 weeks of C1-INH. A total of 22 patients were crossed-over to the second arm of the study. Patients received twice-weekly doses of C1-INH or placebo. The primary endpoint was met with a 52% reduction in the number of attacks in the C1-INH group ($p<0.0001$). Secondary endpoints in the study also showed highly significant differences in favor of C1-INH, including a 66% reduction in days of swelling ($p<0.0001$) and decreases in the average severity of attacks ($p=0.0008$) and average duration of attacks ($p=0.0004$). Based on the positive results of this study, we amended our BLA filing with the FDA on October 30, 2007. Our product candidate was well tolerated with an adverse event profile no different from placebo. The most common adverse reactions observed were injection site rash and lightheadedness. No drug-related serious adverse events, no immunogenicity and no decrease in efficacy have been observed in the trials.

On January 30, 2008, we announced our receipt of a complete response letter from the FDA regarding our BLA for Cinryze™ for the acute and prophylactic treatment of HAE. In our announcement, we stated that the FDA requested information with respect to chemistry, manufacturing and controls, as well as additional analyses of existing efficacy data from the Cinryze™ trials. While no new clinical trials were requested in this letter, no assurances can be given that additional clinical studies will not be requested in the future or on the timing of any further FDA action. We are in the process of compiling our response to the information requested by FDA. In addition, we have been advised that the U.S. Food and Drug Administration's Blood Products Advisory Committee, or BPAC, intends to review our BLA for Cinryze on May 2, 2008, for the prophylactic treatment of HAE.

The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the BLA. Accordingly, there can be no assurance that the outcome of our Phase III trials will be successful or that the results of the trials will support licensure by the FDA. If approved, we intend to commercialize Cinryze™ through a specialty sales force in the United States.

Acute Myocardial Infarction

Background

AMI, commonly known as a heart attack, is a sudden, life-threatening cardiac disorder caused by an obstruction of blood flow to the heart. The major symptom of AMI is chest discomfort, but associated symptoms include nausea, vomiting, shortness of breath and dizziness. AMIs vary in severity and symptoms, and the intensity of the symptoms depends on the size of the area of heart muscle affected by the infarction. Clinical diagnosis of AMI is typically based on elevation of two cardiac enzyme markers, creatine kinase and troponin, markers considered highly reliable measures of cardiac injury.

AMI results in the development of myocardial necrosis, or death of heart cells or tissue, due to ischemia (lack of oxygen). The heart cells are not supplied with sufficient oxygen to meet their metabolic requirements. The most common cause of AMI is atherosclerosis or the accumulation of plaques in the arterial wall. Plaques can rupture and form a thrombus, or clot, that partially or totally blocks arterial blood flow. Patients with this condition suffer the disruption of the normal pattern of contractions of the heart muscle leading to atrial fibrillation (rapid uncontrolled beat) and/or heart failure. There are approximately 865,000 patients with AMI in the United States annually, resulting in an estimated 171,000 directly attributable deaths.

Current Treatments of AMI

Current treatments of AMI are limited and are aimed at restoring blood flow, improving tissue oxygenation and preventing further arterial obstruction. The first line of treatment usually includes oxygen (to reduce the workload of the heart), aspirin (to inhibit further clot formation), nitroglycerin (to reduce the oxygen requirements of the heart) and morphine (for pain). Fibrinolytic drugs, such as streptokinase, urokinase or alteplase, are administered to dissolve clots, and heparin is given as an anticoagulant to prevent further clot formation. Percutaneous transluminal coronary angioplasty, or PTCA, is commonly performed to restore blood flow to the affected coronary artery, a procedure that may involve the placement of a stent to prevent closure of the vessel. In some cases, coronary arterial bypass graft surgery may be required. Antiplatelet medications, such as aspirin and clopidogrel, have become a cornerstone of therapy for AMI. These medications prevent the accumulation of platelets, a trigger event in clot formation. Newer strategies include the use of platelet glycoprotein IIb-IIIa receptor inhibitors, low molecular weight heparin, and Factor Xa inhibitors.

C1-INH for the Treatment of AMI

Current treatments for AMI, both surgical and pharmaceutical, are directed at restoring blood flow to heart tissue or preventing further obstruction. The later stages of cardiac cell injury during AMI, however, result at least in part from an inflammatory response. Activation of the complement system has been demonstrated, inflammatory mediators have been identified, and certain anti-inflammatory drugs have been shown to reduce infarct size in animal models. Despite a widespread appreciation for the role of inflammation in AMI in both the scientific and medical communities, no presently available treatments directly target the mechanisms of inflammation. Based on preliminary animal and clinical data, we believe that C1-INH may be useful as a treatment for AMI.

Two of the major inflammatory pathways believed to be involved in AMI are the complement system and the contact pathway of intrinsic coagulation. C1-INH is an important inhibitor of both of these pathways and, therefore, may provide a therapeutic benefit in the treatment of AMI. C1-INH has been studied extensively in animal models of myocardial infarction in rat, pig, cat and dog models. In these studies, C1-INH was shown both to restore blood flow and to reduce cardiac damage. The use of C1-INH in treating AMI has also been studied in a preliminary clinical trial published in the European Heart Journal in 2002. In 13 patients, release of troponin T and creatine kinase MB, two accepted biochemical markers of cardiac damage, were reduced by 36% and 57%, respectively, compared to 18 controls. We entered into an exclusive worldwide license with Sanquin for the use of C1-INH for the treatment of AMI.

The supply of plasma derived C1-INH may not be sufficient for the treatment of AMI. Based on the rights we obtained from Sanquin, as described below, we intend to initiate a research program for the development of a genetically engineered or recombinant version of C1-INH.

Distribution, Manufacturing and Licensing Relationships

Distribution and Manufacturing Services Agreement with Sanquin

We entered into a Distribution and Manufacturing Services Agreement with Sanquin as of January 16, 2004. Under this agreement, Sanquin has granted us (i) the exclusive right to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma manufactured by Sanquin for the treatment of HAE in Israel and in all countries in North America and South America (other than the Dutch Overseas Territories, Argentina and Brazil), and (ii) a right of first refusal to distribute, market, offer for sale, sell, import and promote C1-INH derived from human plasma manufactured by Sanquin for the treatment of HAE in certain other geographic regions and under certain conditions.

Under the distribution agreement, it is our responsibility to conduct the Phase III clinical trials of C1-INH for the treatment of HAE and to prepare and file all regulatory applications necessary to register the product candidate. In exchange, Sanquin agreed to provide us with the technical data and support necessary to assist us in preparing and filing all such regulatory applications.

Furthermore, Sanquin agreed to supply C1-INH for our Phase III clinical trials. Upon receipt of FDA approval for our product candidate for the treatment of HAE, upon commercial launch of this product and thereafter during the term of the agreement, Sanquin will supply us with our commercial requirements for C1-INH for the treatment of HAE in each country where we have received regulatory approval subject to minimum annual purchase requirements in Euros equal to approximately $21.7 million per year. The initial term of this agreement expired on December 31, 2007 and we exercised our right to extend the term through December 31, 2010.

2007 Amendment to Distribution and Manufacturing Services Agreement

On October 10, 2007, we entered into an amendment, dated as of September 24, 2007, to our Distribution and Manufacturing Services Agreement with Sanquin. Pursuant to this amendment, Lev and Sanquin will initiate a construction project to scale-up the production facilities of Sanquin to be used for the purpose of meeting our anticipated ongoing requirements for the commercial use of the C1-Inhibitor product. Pursuant to the terms and conditions of the amendment, we will jointly develop a project plan for the construction to the production facilities with Sanquin. Subject to the terms of the final project plan, we would provide Sanquin with a non-interest bearing loan, up to a maximum amount of €7.5 million (approximately US $11.0 million, based on the exchange rate as of December 31, 2007), to finance the construction project. This loan will be due July 1, 2014 and Sanquin agreed to repay the principal amount of the loan by providing us with a discount to the per unit purchase price of product. In addition, in the event the agreement is terminated before July 1, 2014 because of a default by us or if by such date the volume of product we order is less than the required volume for Sanquin to repay the loan, then we shall waive the then outstanding balance of the loan. In the event the agreement is terminated because of a default of Sanquin prior to the loan being repaid in full, then Sanquin shall pay us the entire outstanding principal balance of the loan as of the date of termination within 60 days from such date.

Pursuant to the amendment, Sanquin shall manufacture product for us on a toll-manufacturing basis using blood plasma we supply. We agreed to purchase a specified amount of product from Sanquin until the scale up is complete, which we expect to occur during the first fiscal quarter of 2009. In addition, we agreed to an annual minimum purchase commitment of product during the term of the agreement commencing in the year in which the scale up is approved in the U.S. for commercial production. The parties agreed to negotiate in good faith to modify these requirements in the event that regulatory approval for commercial release of the product in the U.S. does not occur by March 31, 2008. Our contractual purchase commitments are subject to annual adjustments based on market conditions and do not include the cost of storage, handling and testing services that Sanquin will provide for us.

Further, pursuant to the amendment, Sanquin agreed to transfer to us and/or one or more third parties, all necessary rights and interests to its technology for manufacturing the product to enable a third party to serve as a second supplier of product under certain circumstances. The terms and conditions of this transfer are subject to negotiation among Sanquin, Lev and a mutually agreed-upon third party. In addition, Sanquin agreed that in the event of a change in control of Sanquin (as defined in the amendment), we shall have the right to acquire from Sanquin a joint ownership right to the technology to enable us to exploit the technology, including to transfer the technology to a third party for the purpose of manufacturing product (and terminating or reducing its obligation to purchase from Sanquin). If we exercise this right, we would pay Sanquin a down payment against future annual license fees and royalties and be obligated to pay such future fees and royalties as provided for in the amendment. As provided for in the amendment, the agreement between Lev and Sanquin shall be effective through December 31, 2010, and thereafter, we shall have the sole right to extend the initial term for up to an additional 18 years by providing for six consecutive renewal terms of three years each; and thereafter, the Agreement may be extended by the mutual consent of the Parties.

Services Agreement

In September 2006 we engaged Sanquin to provide us with clinical laboratory testing services to conduct diagnostic tests on blood samples derived from our clinical trials to assist us in establishing the safety and efficacy of C1-INH for HAE.

For these services, we paid Sanquin a professional services fee for the tests they conduct during the term of the engagement. This services agreement expired July 1, 2007.

Exclusive License Agreement with Sanquin

We entered into a license agreement with Sanquin on January 27, 2004. Under this agreement, we have an exclusive, worldwide, royalty-bearing license, with the right to sublicense Sanquin patent rights and know-how relating to the use of C1-INH for the treatment of AMI. In connection with the license agreement, we paid Sanquin certain fees and reimbursed Sanquin for certain expenses. In addition, we have an obligation to pay Sanquin royalties on sales of products incorporating the licensed technology.

We are required to create a comprehensive research plan for the commercial exploitation of the licensed technology. We are continuing to work with Sanquin on the design of the research plan. We agreed to commit a minimum of $125,000 per annum during the first three years following the execution of the license agreement toward research on the licensed technology conducted by Sanquin and other parties. As of March 1, 2008, we have funded approximately $141,000 to third parties engaged in this research. As of December 31, 2007, we have accrued the remaining obligation of $234,000. In addition, we have agreed to use commercially reasonable efforts to manufacture and market products incorporating the licensed technology. If funding permits, we intend to initiate a research program in 2008 for the development of a genetically engineered or recombinant version of C1-INH to be used in the treatment of AMI.

The license agreement, unless it is terminated earlier, shall continue in force until the expiration, invalidation or unenforceability of the last to expire patent licensed pursuant to the agreement. The U.S. patent licensed from Sanquin will expire on July 18, 2017, provided that applicable maintenance fees are timely paid. Either party may terminate the agreement in the event of an uncured material breach by the other.

Supply Agreements

On July 19, 2007, we entered into an agreement for the purchase and sale of plasma with DCI Management Group, LLC pursuant to which we will purchase quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation. Under the agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. We are committed to purchase a minimum of $13,950,000 of product during 2008. Thereafter we expect our annual purchase commitment to be between $12.2 million and $12.9 million for the balance of the term of the agreement. Our contractual purchase commitments are subject to annual percentage increases based on market conditions and do not include the cost of additional pre-delivery testing which we may require the supplier to undertake. We estimate our remaining commitment under this agreement to be approximately $51.7 million.

The agreement expires December 31, 2011, unless sooner terminated in accordance with its terms. Either party may terminate the agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. Subject to the supplier's ability to mitigate damages, in the event we are in default of our payment obligation under the contract, we will be liable to purchase the minimum quantities of plasma specified under the contract for the balance of the term. We have the right, however, to terminate the contract if by December 31, 2008 we do not obtain regulatory approval for the commercialization of our lead product candidate or are not able to secure adequate financial arrangements to cover our obligations with respect to the initial purchase commitments under the agreement. In either such event, we will be obligated to complete the purchase of 80% of the initial minimum purchase commitment, subject to the supplier's ability to mitigate damages. Upon expiration of the agreement, or in the event the agreement is terminated for reasons other than as set forth above, we will be obligated to purchase a closing inventory of plasma in the quantity specified in the agreement.

In connection with our entry into the agreement, we signed a letter agreement with our prior plasma supplier pursuant to which the supplier agreed to waive its right to supply us with additional quantities of plasma and to reduce its commitment under such agreement. Following our agreement to purchase an additional amount of approximately $353,000 of plasma under such agreement during 2007, which we satisfied, the parties agreed to suspend further purchases under this agreement until such time as a new definitive agreement is entered into between the parties. In consideration of the foregoing, we agreed to waive our right to have the supplier cover a percentage of the cost of replacement plasma we are

acquiring from the new supplier.

Intellectual Property

The following factors are important to our success:

- receiving patent protection for our product candidates;
- not infringing the intellectual property rights of others;
- preventing others from infringing our intellectual property rights; and
- maintaining our patent rights and trade secrets.

We actively seek, when appropriate, protection for our proposed products, technologies and proprietary information through.United States and foreign patents. In addition, we rely upon trade secrets and contractual arrangements to protect our proprietary information.

As of December 31, 2007, under our license agreement with Sanquin, we license a United States patent and an International Patent Application including any foreign patents issuing therefrom related to our technologies, compounds and their applications in pharmaceutical development or their use as pharmaceuticals and in particular for the use of C1-INH in the treatment of AMI. We face the risk that our licensed patent and any patents issued to us in the future may be challenged or circumvented or may otherwise not provide protection for any commercially viable products that we develop. We also note that United States patents and patent applications may be subject to interference proceedings and/or reexamination proceedings in the United States Patent and Trademark Office (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the very patent rights sought by us, which in turn could affect our ability to market a potential product to which that patent filing was directed. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful, would result in the entire loss of our patent or the relevant portion of our patent and not just with respect to that particular infringer. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations.

In addition, our ability to assert our patents against a potential infringer, depends on our ability to detect the infringement in the first instance. Many countries, including certain European countries, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties in some circumstances (for example, when the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection.

Our success will also depend in part upon our not infringing patents issued to others. If our product candidates are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited.

Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, if a patent infringement suit were brought against us or our future strategic partners or licensees, if any, we or they may be forced to stop or delay developing, manufacturing or selling potential products that are alleged to infringe a third party's intellectual property unless that party grants us or our strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any

licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we or our strategic partners or licensees were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Much of our technology and many of our processes depend upon the knowledge, experience and skills of our scientific and technical personnel. To protect rights to our proprietary know-how and technology, we generally require all employees, contractors, consultants, advisors, visiting scientists and collaborators as well as potential collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information. The agreements with employees and consultants also require disclosure and assignment to us of ideas, developments, discoveries and inventions. These agreements may not effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information.

Trademarks

We have sought to register a number of trademarks in the US and in certain foreign jurisdictions, including the trademarks "Lev Pharma" and "Cinryze". These applications are currently pending and no assurance can be given that registration will be obtainable or if obtained, will be effective to protect our trademarks. Certain third parties, however, have opposed our trademark application for "Lev Pharma" with the U.S. Patent and Trademark Office and with the Community Trade Marks Office of the European Union. We are vigorously contesting these proceedings and do not believe that they will have a material adverse effect on our business, results of operations or financial condition. However, no assurances can be given that such belief will ultimately prove to be accurate, in which case the ultimate resolution of these matters could potentially have a material adverse effect on our business.

Competition

We operate in an industry characterized by intense competition and rapid technological change. New developments occur and are expected to continue to occur at a rapid pace. Discoveries or commercial developments by our competitors may render some or all of our technologies, products or potential products obsolete or non-competitive.

Our principal focus is on the development of therapeutic products. We conduct research and development programs to develop and test product candidates and demonstrate to appropriate regulatory agencies that these products are safe and effective for therapeutic use in particular indications. Our principal competitors are companies that are already marketing products in those indications or are developing new products for those indications. Most of these organizations have greater financial resources and drug development experience than we do. Companies developing therapeutics for the treatment of HAE include Dyax Corp., Jerini AG, Pharming Group N.V. and CSL Behring. Other competitors and potential competitors include companies that market and develop anabolic steroid-based drugs and anti-inflammatory compounds.

HAE is a disease that fits within the definition of the Orphan Drug Act, and therefore any company that develops a therapy for this indication could, upon licensure, obtain a seven year marketing exclusivity in the United States for the licensed indication. We believe CSL Behring and Pharming Group N.V. are currently developing therapy for the acute treatment of HAE that the FDA may consider the same as ours under the Orphan Drug Act. In the event that these companies obtain FDA product licensures before us, we could be prevented from obtaining FDA licensure and marketing our C1-INH product for the acute treatment of HAE for up to seven years.

For potential cardiovascular disease product applications, our potential competitors include numerous pharmaceutical and biotechnology companies, most of which have substantially greater financial resources and experience than we do.

Sales and Marketing

Although we do not currently have any commercial products, we have been designing our proposed marketing and sales strategy for a commercial launch of Cinryze. During 2006, we began to assemble a small, highly-focused sales and marketing force. During fiscal 2007, we continued to augment our internal commercial capabilities by hiring additional employees, including a senior vice president of commercial operations and vice president of sales. Our current plan is to

develop an internal sales organization of approximately ten U.S. based representatives to address our sales efforts. We currently expect to hire additional sales and marketing personnel proximal to obtaining regulatory approval for our lead product candidate. In order to enable the broadest commercialization of our product candidates and to cover all of the key prescribing physicians at an adequate level of reach and frequency, we are engaged in negotiations with a limited number of large, established specialty pharmacy and distribution companies that would provide us with logistics and distribution capabilities. We expect to focus our distribution efforts towards hospitals, allergists, immunologists and home healthcare. Management is continuing to analyze and evaluate our internal sales and marketing needs as well as our distribution plans in line with the regulatory developments regarding our lead product candidate.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of pharmaceuticals, and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical drugs are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases, state statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources.

Regulatory approval, when and if obtained for any of our product candidates, may be limited in scope which may significantly limit the indicated uses for which our product candidates may be marketed. Further, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown problems that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

FDA Requirements

Preclinical Studies

Before testing any compounds with potential therapeutic value in human subjects in the United States, stringent government requirements for preclinical data must be satisfied. Preclinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical testing results obtained from studies in several animal species, as well as from *in vitro* studies, are submitted to the FDA as part of an investigational new drug application, or IND, and are reviewed by the FDA prior to the commencement of human clinical trials. This preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers.

Clinical Trials

If a company wants to test a new drug in humans, an IND must be prepared and filed with the FDA. The IND becomes effective if not rejected or put on clinical hold by the FDA within 30 days. In addition, an Institutional Review Board comprised in part of physicians at the hospital or clinic, as well as others representing the interests of the community where the proposed trials will be conducted, must review and approve the trial protocol and monitor the trial and the investigators on an ongoing basis. The FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Clinical Trial Phases

Clinical trials typically are conducted in three sequential phases, phases I, II and III, with phase IV trials potentially conducted after marketing approval. These phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase I clinical trials.* After an IND becomes effective, Phase I human clinical trials can begin. These trials evaluate a drug's safety profile, and the range of safe dosages that can be administered to healthy volunteers and/or patients, including the maximum tolerated dose that can be given to a trial subject with the target disease or condition. Phase I trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

- *Phase II clinical trials.* Phase II clinical trials typically are designed to evaluate the potential effectiveness of the drug in patients and to further ascertain the safety of the drug at the dosage given in a larger patient population.

- *Phase III clinical trials.* In Phase III clinical trials, the drug is usually tested in a controlled, randomized trial comparing the investigational new drug to an approved form of therapy in an expanded and well-defined patient population and at multiple clinical sites. The goal of these trials is to obtain definitive statistical evidence of safety and effectiveness of the investigational new drug regime as compared to an approved standard therapy in defined patient populations with a given disease and stage of illness.

- *Phase IV clinical trials.* The FDA may require post-approval studies, known as Phase IV studies, to develop additional information regarding the product. In addition, the FDA requires post-approval adverse event reporting, and the agency has the power to require changes in labeling or to prevent further marketing of a product. The FDA may also decide later to withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market.

Biologics License Application

After completion of clinical trials, if there is substantial evidence that the drug is safe, pure and potent, a biologics license application, or BLA, is prepared and submitted for the FDA to review. The BLA must contain all of the essential information on the drug gathered to that date, including data from preclinical and clinical trials, and the content and format of a BLA must conform with all FDA regulations and guidelines. Accordingly, the preparation and submission of a BLA is a major undertaking for a company. In addition, the FDA reviews a BLA to determine whether the facility in which a product is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

The FDA reviews all BLAs submitted before it accepts them for filing and may request additional information from the sponsor rather than accepting a BLA for filing. In such an event, the BLA must be submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. By law, the FDA has 180 days in which to review the BLA and respond to the applicant. The review process is often significantly extended by the FDA through requests for additional information and clarification. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, other scientific experts and patient representatives, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation, but gives great weight to it. If the FDA evaluations of both the BLA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which may contain a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the BLA submission or manufacturing facility is not favorable, the FDA may refuse to approve the BLA or issue a not approvable letter. Before the FDA determines whether to approve our products, we expect our approval applications to be reviewed by the BPAC, an advisory committee convened by and reporting to the FDA. We have been advised that BPAC, intends to review our BLA for Cinryze on May 2, 2008, for the prophylactic treatment of HAE.

Fast Track Designation / Priority Review

We have received Fast Track designation from the FDA for Cinryze™ for the acute and prophylactic treatment of HAE. Congress enacted the Food and Drug Administration Modernization Act of 1997 (the "Modernization Act") in part to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the development and review for certain new products. The Modernization Act establishes a statutory program for the review of Fast Track products, including biologics. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast

Track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product, prior to marketing.

The Modernization Act provides that the FDA can base approval of a marketing application for a Fast track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. The FDA may condition approval of an application for a Fast track product on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a Fast track product in an expedited manner on a number of grounds, including the sponsor's failure to conduct any required post-approval study in a timely manner.

On October 1, 2007, the FDA accepted for filing and assigned Priority Review status to our BLA for Cinryze™. Priority Review is granted to products that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. The goal for reviewing a product with Priority Review status is six months from the filing date.

On January 30, 2008, we announced our receipt of a complete response letter from the FDA regarding our BLA for Cinryze™ for the acute and prophylactic treatment of Hereditary Angioedema. In our announcement, we stated that the FDA requested information with respect to chemistry, manufacturing and controls, as well as additional analyses of existing efficacy data from the Cinryze™ trials. While no new clinical trials were requested in this letter, no assurances can be given that additional clinical studies will not be requested in the future or on the timing of any further FDA action. We are in the process of compiling our response to the information requested by FDA. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the BLA. Accordingly, there can be no assurance that the FDA will ultimately approve our BLA. If approved, we intend to commercialize Cinryze™ through a specialty sales force in the United States.

Other Regulatory Requirements

Any products that we manufacture or distribute under FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with current good manufacturing processes ("cGMP") regulations which impose procedural and documentation requirements upon us and any third party manufacturers we utilize. Before approving a biologics license application, the FDA will inspect the facilities at which the product is manufactured (including both those of the applicant and any third-party component manufacturers) and will not approve the product unless the manufacturing facilities are in compliance with FDA's cGMP, which are regulations that govern the manufacture, storage and distribution of a product. Manufacturers of biologics also must comply with FDA's general biological product standards.

Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP regulations. We must ensure that any third-party manufacturers continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The FDA also closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new indications for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action, either in the United States or abroad.

In addition, the labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and U.S. Federal Trade Commission ("FTC") requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet and direct-to-consumer advertising. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing the company to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution.

Approvals Outside of the United States

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. There is no assurance that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

Employees

As of March 3, 2008, we had 26 employees. We consider our relationship with our employees to be satisfactory.

General

Our principal executive office is located at 675 Third Avenue, Suite 2200, New York, New York 10017 and our telephone number is (212) 682-3096.

Executive Officers

Our executive officers are:

Name	Age	Position
Joshua D. Schein, Ph.D.	47	Chief Executive Officer and Director
Judson Cooper	49	Chairman of the Board, Executive Vice President and Secretary
Douglas J. Beck	47	Chief Financial Officer
Dov Elefant	40	Corporate Controller

Joshua D. Schein, Ph.D. has been our Chief Executive Officer and a Director since December 29, 2004 and Chief Executive Officer and a Director of Lev Development Corp., or LDC, since the commencement of LDC's operations in July 2003. Dr. Schein is also a founder of SIGA Technologies, Inc., a publicly traded biotechnology company, and served as its Chief Executive Officer from August 1998 to April 2001. Dr. Schein also served as SIGA's acting Chief Executive Officer from April 1998 to August 1998, as Secretary and a Director from December 1995 to April 2001, and as Chief Financial Officer from December 1995 until April 1998. Dr. Schein is also a founder of DepoMed, Inc., a publicly traded drug delivery company, and served as a director of the company from December 1995 to June 1998. From January 1996 to August 1998, Dr. Schein was an executive officer and a director of Virologix Corporation, a private biotechnology company that he co-founded and which was subsequently acquired by Access Pharmaceuticals, a publicly traded biotechnology company. From June 1996 to September 1998, Dr. Schein was an executive officer and a director of Callisto Pharmaceuticals, Inc., a publicly traded biotechnology company that he co-founded. Dr. Schein is also a founder of Hemoxymed, Inc., a publicly traded biotechnology company. Since 1997, Dr. Schein has been a principal of Prism

Ventures LLC, a privately held limited liability company focused on the biotechnology industry. From 1994 to 1995, Dr. Schein served as a Vice President of Investment Banking at Josephthal, Lyon and Ross, Incorporated, an investment banking firm. Dr. Schein received a Ph.D. in neuroscience from the Albert Einstein College of Medicine, an MBA from the Columbia Graduate School of Business, and a B.A. in biochemistry from Brandeis University.

Judson Cooper has been our Chairman of the Board, Executive Vice President and Secretary since December 29, 2004 and Chairman of LDC since the commencement of operations of LDC in July 2003 and Executive Vice President since November 1, 2004. Mr. Cooper is also a founder of SIGA Technologies, Inc., a publicly traded biotechnology company, and served as its Chairman from August 1998 to April 2001. Mr. Cooper also served as SIGA's acting Chairman from April 1998 to August 1998, as a Director from December 1995 to April 2001, as Executive Vice President from November 1996 to April 2001, and as its founding President from December 1995 to November 1996. Mr. Cooper is also a founder of DepoMed, Inc., a publicly traded drug delivery company and served as a director of the company from December 1995 to June 1998. From January 1996 to August 1998, Mr. Cooper was an executive officer and a director of Virologix Corporation, a private biotechnology company that he co-founded and which was subsequently acquired by Access Pharmaceuticals, a publicly traded biotechnology company. From June 1996 to September 1998, Mr. Cooper was an executive officer and a director of Callisto Pharmaceuticals, Inc., a publicly traded biotechnology company that he co-founded. Mr. Cooper is also a founder of Hemoxymed, Inc., a publicly traded biotechnology company. Since 1997, Mr. Cooper has been a principal of Prism Ventures LLC, a privately held limited liability company focused on the biotechnology industry. Mr. Cooper is a graduate of the Kellogg School of Management.

Douglas J. Beck is a CPA and has been our Chief Financial Officer since May 23, 2005. He was our controller from February 21, 2005 until May 22 2005. From September 2004 to October 2004, Mr. Beck served as a consultant to Pfizer, Inc. From December 2002 to September 2004, Mr. Beck served in various capacities with Henry Bros. Electronics, Inc. (f/k/a Diversified Security Solutions, Inc.), from Director of Finance to Chief Financial Officer. From November 2000 to December 2002, Mr. Beck was a financial consultant to various companies. From March 2000 to October 2000, Mr. Beck served as Director of Financial Reporting for Urbanfetch.com, Inc. and from December 1998 to March 2000, Mr. Beck was an audit manager with Andersen LLP. Mr. Beck holds a B.S. from the Fairleigh Dickinson University.

Dov Elefant became our Corporate Controller as of March 16, 2007. Prior to joining Lev Pharmaceuticals, Dov S. Elefant held numerous financial positions from December 1999 to March 2007 at EpiCept Corporation, a publicly-traded pharmaceutical company. Most recently, Mr. Elefant was the Controller and Vice President of Finance and Administration from April 2004 to March 2007. Mr. Elefant's other positions with EpiCept included Chief Financial Officer and Vice President of Finance and Administration. From October 1998 until December 1999, Mr. Elefant was Assistant Controller of Alteon Inc., a publicly traded biopharmaceutical company. Prior to that, he served as Director of Accounting and Finance of Innapharma, Inc., a biopharmaceutical company. Mr. Elefant received his B.S. in Accounting from the Sy Syms School of Business of Yeshiva University in New York.

Available Information

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance with such laws we file annual, quarterly and current reports and other information with the Securities and Exchange Commission (the "SEC"). The SEC maintains a website that contains annual, quarterly and current reports, proxy and information statements and other information filed with the SEC. The SEC's website address is http://www.sec.gov. You may also read and copy any document we file with the SEC at the SEC's public reference room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of its public reference room. The information we file with the SEC and other information about us is also available on our website at http://www.levpharma.com. However, the information on our website is not a part of, nor is such information to be deemed incorporated by reference into, this annual report.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors and the other information included herein as well as the information included in other reports and filings made with the SEC. If any of the matters or events described in the following risks actually occurs, our business, financial condition or results of operations could be harmed. In addition, the trading price of our common stock could decline due to any of these risks.

Risks related to our business

We are at an early stage of development as a company and currently have no source of revenue and may never become profitable.

We are a development stage biopharmaceutical company with a limited operating history. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue. Our ability to generate revenue depends on: first, obtaining FDA marketing approval for any of our products and, second, successfully commercializing and bringing to market these products. In particular, if we do not successfully develop and commercialize C1-INH for the treatment of HAE, we will be unable to generate any revenue for many years, if at all and, even if successful in obtaining FDA marketing approval for C1-INH for the treatment of HAE, it may be up to a year or more before we can expect to begin to generate revenue. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of December 31, 2007, we had a deficit accumulated during our development stage of $51,269,765. We have from our inception incurred and will continue to incur significant and increasing operating losses for the next several years as we pursue FDA approval of our BLA for C1-INH for the acute and prophylactic treatment of HAE, continue the open-label studies of C1-INH and advance C1-INH for the treatment of selected cardiovascular diseases into clinical development. For the years ended December 31, 2005, 2006 and 2007, we incurred net losses of $6,308,356, $11,767,489, and $28,081,426, respectively. In addition, if we receive regulatory approval of any of our product candidates, we expect to incur significant sales and marketing expenses in the future. Because of the numerous risks and uncertainties associated with developing and commercializing these product candidates, we are unable to predict the extent of future losses or when and if we will generate revenues or become profitable.

We currently are devoting substantially all of our efforts on the development of product candidates based on C1-INH. If we are unable to successfully develop and commercialize these product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially harmed.

We are investing substantially all of our time and resources to the development of C1-INH for the treatment of inflammatory diseases. Our ability to generate product revenues, if ever, depends on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
- competition from other therapies; and

- a continued acceptable safety profile of our C1-INH-based products following approval.

Given our limited focus on C1-INH product candidates, if these product candidates do not prove successful in clinical trials, and are not approved or are not commercialized because we have insufficient resources for continued development for any other reason, we may be required to suspend or discontinue our operations and our business could be materially harmed.

We are a development stage company, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues;
- limited marketing and manufacturing experience;
- an expected reliance on third parties for the development and commercialization of some of our proposed products;
- a competitive environment characterized by numerous, well-established and well-capitalized competitors;
- uncertain market acceptance of our proposed products; and
- reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

We expect that we may need to raise substantial additional capital to fund our operations, and our failure to obtain funding when needed would adversely affect our development programs and other operations.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- complete the clinical development of C1-INH for the treatment of HAE;
- continue the development of our other product candidates;
- finance our general, administrative and license acquisition costs;
- prepare regulatory filings for C1-1NH and our other product candidates;
- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- develop and implement sales, marketing and distribution capabilities.

Our cash used in operations increased significantly over the period from July 21, 2003 (inception) to December 31, 2007 and we expect that our cash used in operations will increase significantly over the next several years. Based on our current levels of research and development and our business plan, we believe that our existing cash and cash equivalents of approximately $21.9 million should be sufficient to fund our anticipated levels of operations for the next six months. Based on the foregoing, we have received an audit report from our independent registered public accounting firm

containing an explanatory paragraph stating that our historical recurring losses from operations raise substantial doubt about our ability to continue as a going concern. We do not have any commercial products available for sale and have not generated significant revenues and there is no assurance that if approval of our products is received that we will be able to generate cash flow to fund operations. Due to the foregoing factors, we expect that we may need to raise additional capital to complete the development and commercialization of our current product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other development activities;
- any future decisions we may make about the scope and prioritization of the programs we pursue;
- the costs and timing of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- ongoing determinations of the potential commercial success of our proposed products;
- the costs involved in utilizing third party contract research organizations for preclinical studies and clinical trials;
- the availability of third parties, and the cost, to manufacture compounds for clinical trial supply;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- general market conditions for offerings from biopharmaceuticals companies.

To date, our sources of cash have been primarily limited to the sale of equity and debt securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital, when required, or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and /or the commercialization of one or more of our product candidates. Accordingly, any failure to raise adequate capital in a timely manner would have a material adverse effect on our business, operating results, financial condition and future growth prospects. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- relinquish, license or otherwise dispose of rights to technologies, on unfavorable terms, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If either of our agreements with Sanquin terminate, we may be unable to continue our business.

Our business is highly dependent on distribution and license rights that we have received from Sanquin pursuant to a distribution agreement relating to the treatment of HAE and a license agreement relating to the treatment of AMI. Upon commercial launch of our product candidate for the treatment of HAE and thereafter during the term of the agreement, Sanquin will supply us with our commercial requirements for C1-INH for the treatment of HAE in each country where we have received regulatory approval, subject to minimum annual purchase requirements in Euros equal to approximately $21.7 million per year. If we fail to fulfill certain obligations or fail to meet certain milestones under the distribution agreement, the distribution agreement may be terminated. These milestones include (a) submission of a BLA with the FDA within 12 months from the completion of the clinical trial for HAE, and (b) obtaining marketing approval in the United States within 18 months from the submission of the BLA. In addition, Sanquin has the right to terminate the agreement if it is unable to maintain liability insurance for its United States obligations, under certain circumstances as described in the distribution agreement. In addition, either party may terminate the agreement upon an uncured breach. If Sanquin terminates the distribution agreement, we would have to retain another supplier of C1-INH for the treatment of HAE. If we are unable to locate another supplier of C1-INH comparable to Sanquin on economically acceptable terms, or at all, we will not be able to commercialize our product candidates and we may be forced to cease our operations.

Under the license agreement, Sanquin granted us an exclusive license to use certain patent, patent applications and know-how related to the use of C1-INH technology for the treatment of AMI. Under the terms of the license agreement for AMI, we are obligated to make minimum and earned royalty and other payments to Sanquin. If we fail to fulfill those obligations

or other material obligations, the license agreement may be terminated by Sanquin. If Sanquin terminates the license agreement, we will have no further rights to utilize the intellectual property covered by the license agreement, we would not be able to commercialize the applicable product candidate for the treatment of AMI and we may be forced to cease our operations relating to the treatment to AMI using C1-INH, particularly if we do not have rights to other product candidates.

We are dependent on Sanquin as our sole source of supply for C1-1NH.

Pursuant to our distribution agreement with Sanquin, Sanquin will supply us with certain annual minimum and maximum amounts of C1-INH. In the event demand for C-1NH is greater than the amount supplied by Sanquin, we would have to find alternative suppliers of C1-1NH. If we are unable to locate another supplier of C1-1NH comparable to Sanquin on economical terms, or at all, we may lose business and our reputation in the marketplace could be adversely affected.

We agreed to provide Sanquin with a loan to finance the scale up of their production facilities, the repayment of which may be waived in the event we fail to perform under our agreement with them.

On October 10, 2007, we entered into an amendment to our Distribution and Manufacturing Services Agreement with Sanquin. Pursuant to this amendment, Lev and Sanquin agreed to jointly develop a project plan for, and initiate a construction project to scale-up the production facilities of Sanquin to be used for the purpose of meeting our anticipated ongoing requirements for the commercial use of the C1-Inhibitor product. Subject to the terms of the final project plan, we agreed to provide Sanquin with a non-interest bearing loan, up to a maximum amount of €7.5 million (approximately US $11.0 million, based on the exchange rate as of December 31, 2007), to finance the construction project. This loan is due July 1, 2014 and Sanquin agreed to repay the principal amount of the loan by providing us with a discount to the per unit purchase price of product. In the event the agreement is terminated because of a default of Sanquin prior to the loan being repaid in full, then Sanquin shall pay us the entire outstanding principal balance of the loan as of the date of termination within 60 days from such date. However, in the event the agreement is terminated before July 1, 2014 because of a default by us or if by such date the volume of product we order is less than the required volume for Sanquin to repay the loan, then we shall waive the then outstanding balance of the loan.

We rely on third parties to supply and manufacture our product candidates, without any direct control over the timing for the supply, production and delivery of our product candidates, thereby possibly adversely affecting any future revenues.

We have relied exclusively and are dependent on certain third party source suppliers to supply raw materials, specifically plasma, for our product candidates. To date, we have only required plasma for the production of C1-INH to conduct our clinical trials. However, in connection with our ongoing trials and in the event any of our product candidates receives the approval of the FDA, we will need increased supplies of plasma.

On July 19, 2007, we entered into an agreement for the purchase and sale of plasma with DCI Management Group, LLC, the "supplier" pursuant to which we will purchase quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation. Under this agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. Under this agreement, we are committed to purchase a minimum of $13,950,000 of product during 2008. Thereafter we expect our annual purchase commitment to be between $12.2 million and $12.9 million for the balance of the term of the agreement. Our contractual purchase commitments are subject to annual percentage increases based on market conditions and do not include additional pre-delivery testing which we may require the supplier to undertake. This agreement expires December 31, 2011, unless sooner terminated in accordance with its terms. Either party may terminate the agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. Subject to the supplier's ability to mitigate damages, in the event we are in default of our payment obligation under the contract, we will be liable to purchase the minimum quantities of plasma specified under the contract for the balance of the term. We have the right, however, to terminate the contract if by December 31, 2008 we do not obtain regulatory approval for the commercialization of our lead product candidate or are not able to secure adequate financial arrangements to cover our obligations with respect to the initial purchase commitments under the Agreement. In either such event, we will be obligated to complete the purchase of 80% of the initial minimum purchase commitment, subject to the supplier's ability to mitigate damages. Further, upon expiration of the agreement, or in the event that it is terminated for reasons other than as set forth above, we will be obligated to purchase a closing inventory of plasma. In

connection with this new agreement, we signed a letter agreement with our prior plasma supplier pursuant to which they agreed to waive their right to supply us with additional quantities of plasma. In July 2007, we agreed to purchase approximately $353,000 of plasma from our prior supplier during the balance of 2007, which we satisfied, and the parties agreed to suspend further purchases under this agreement until such time as a new definitive agreement is entered into between the parties. In consideration of the foregoing, we agreed to waive our right to have the supplier cover a percentage of the cost of replacement plasma we are acquiring from the new supplier.

The plasma will be utilized for the production of product or materials by Sanquin under our distribution and manufacturing services agreement. We will expend a significant amount of our currently available cash in obtaining a sufficient supply of plasma. This will increase the likelihood that we will need to raise additional capital to fund our operations.

If we are unable to obtain or maintain this level of plasma supply, we will need to obtain our supply from other parties in order to satisfy our expected needs. Establishing additional or replacement suppliers for these materials may take a substantial amount of time. In addition, we may have difficulty obtaining similar supplies 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 our product candidates could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization of our product candidates. As a result, regulatory approval of our product candidates may not be received at all. All these delays could cause delays in commercialization of our product candidates, delays in our ability to generate revenue, and increase our costs.

If any of our product candidates receives the approval of the FDA we expect to rely on Sanquin and possibly another third-party contractor to manufacture our commercial products. If any current or future third-party supplier ceases to supply the products in the quantity and quality we need to manufacture the drug candidates or if the current or future third-party suppliers are unable to comply with current Good Manufacturing Practices, or cGMPs, and other government regulations, the qualification of additional or replacement suppliers could be a lengthy process, and there may not be adequate alternatives to meet our needs, which would negatively affect our business. We may not be able to obtain the necessary materials used in our products in the future on a timely basis, if at all. The FDA and regulatory agencies in other countries also periodically inspect manufacturing facilities, including third parties who manufacture products or active ingredients for us. The FDA and/or applicable foreign regulatory agencies may not believe that the chosen manufacturers have sufficient experience making the dosage forms that we have contracted with them to produce, and may subject those manufacturers to increased scrutiny. Pharmaceutical manufacturing facilities must comply with applicable cGMPs, and manufacturers usually must invest substantial funds, time and effort to ensure full compliance with these standards. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure to comply with applicable regulatory requirements can result in sanctions, fines, delays or suspensions of approvals, seizures or recalls of products, operating restrictions, manufacturing interruptions, costly corrective actions, injunctions, adverse publicity against us and our products and possible criminal prosecutions.

Our proposed products are in the development stages and will likely not be commercially introduced until mid-2008, if at all.

Our proposed products are in the development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. We have not commercially introduced any products and do not expect to do so until mid-2008 at the earliest, depending upon the timing of our completion of clinical trials, our preparation and filing, and the FDA's review, of our biologics license application for our proposed products. We cannot assure you that any of our proposed products will:

- be successfully developed;
- prove to be safe and efficacious in clinical trials;
- meet applicable regulatory standards or obtain required regulatory approvals;
- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs;

- obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or
- be successfully marketed or achieve market acceptance by physicians and patients.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a biologics license application to the FDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased cost to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollments, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our cost, slow down our product development and approval process and delay our ability to generate revenue.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further developments or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our products in the United States and we will not generate any revenue. The FDA regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product is both safe and effective for each indication where

approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory review any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

Before the FDA determines whether to approve Cinryze, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products. If our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with Good Manufacturing Practices.

The FDA has substantial discretion in the approval process and may either refuse to file our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not file or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to make our application approvable. If any of these outcomes occur, we may be forced to abandon our applications for approvals, which might cause us to cease operations.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

If testing of a particular product candidate does not yield successful results, then we will be unable to commercialize that product.

Our product candidates in clinical trials must meet rigorous testing standards. We must demonstrate the safety and efficacy of our potential products through extensive preclinical and clinical testing. Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards and must meet the requirements of these authorities in the United States, including those for informed consent and good clinical practices. We may not be able to comply with these requirements, which could disqualify completed or ongoing clinical trials. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of Cinryze™ or our other product candidates, including the following:

- safety and efficacy results from human clinical trials may show the product candidate to be less effective or safe than desired or those results may not be replicated in later clinical trials;
- the results of preclinical studies may be inconclusive or they may not be indicative of results that will be obtained in human clinical trials;
- after reviewing relevant information, including preclinical testing or human clinical trial results, we may abandon or substantially restructure projects that we might previously have believed to be promising;
- we or the FDA may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks or for other reasons; and

- the effects of our product candidates may not be the desired effects or may include undesirable side effects or other characteristics that interrupt, delay or cause us or the FDA to halt clinical trials or cause the FDA or foreign regulatory authorities to deny approval of the product candidate for any or all target indications.

Data from our completed clinical trials may not be sufficient to support approval by the FDA for Cinryze™ or our other product candidates. The clinical trials of our product candidates may not be completed as or when planned, and the FDA may not approve any of our product candidates for commercial sale. If we fail to demonstrate the safety or efficacy of a product candidate to the satisfaction of the FDA, this will delay or prevent regulatory approval of that product candidate. Therefore, any delay in obtaining, or inability to obtain, FDA approval of any of our product candidates could materially harm our business and cause our stock price to decline.

The FDA may determine our clinical trials data regarding safety or efficacy are insufficient for regulatory approval.

We discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. These discussions are not binding obligations on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. The FDA may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Even if we obtain successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval.

We may take longer to complete our clinical trials than we project, or we may not be able to complete them at all.

A number of factors, including unexpected delays in the initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of a product candidate to meet required standards for administration to humans may cause significant delays in the completion of our clinical trials. In addition, it may take longer than we project to achieve study endpoints and complete data analysis for a trial. Even if our product candidates proceed successfully through clinical trials and receive regulatory approval, there is no guarantee that an approved product can be manufactured in commercial quantities at reasonable cost or that such a product will be successfully marketed.

We rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also rely on clinical research organizations to perform much of our data management and analysis. They may not provide these services as required or in a timely manner.

If we fail to commence, complete or experience delays in present or planned clinical trials, in particular any additional trials for Cinryze™ that could be required in advance of, or as a condition to, FDA approval, our ability to conduct our business as currently planned could materially suffer. Our development costs will increase if we are required to complete additional or larger clinical trials for Cinryze™ prior to FDA approval or with respect to other product candidates. If the delays or costs are significant, our financial results and our ability to commercialize Cinryze™ or our other product candidates will be adversely affected.

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community.

Our product candidates have never been commercialized in the United States for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe our product candidates, in which case we could not generate revenue or become profitable. Market acceptance of C1-INH for the treatment of HAE and our other product candidates by physicians, healthcare payors and patients will depend on a number of factors, including:

- acceptance by physicians and patients of each such product as a safe and effective treatment;
- cost effectiveness;
- adequate reimbursement by third parties;

- potential advantages over alternative treatments;
- relative convenience and ease of administration; and
- prevalence and severity of side effects.

If our product candidates are unable to compete effectively with marketed treatments, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many products are either under development or are currently marketed for the treatment of HAE and AMI. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize competing products that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Because we will most often be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing products. If we are unable to compete effectively and differentiate our products from currently marketed products, we may never generate meaningful revenue.

If we are not first to market for our HAE product, the Orphan Drug Act may provide a competitor with up to seven years of market exclusivity.

The Orphan Drug Act was created to encourage companies to develop therapies for rare diseases by providing incentives for drug development and commercialization. One of the incentives provided by the act is seven years of market exclusivity for the first product in a class licensed for the treatment of a rare disease. HAE is considered to be a rare disease under the Orphan Drug Act, and companies may obtain orphan drug status for therapies that are developed for this indication. We believe CSL Behring and Pharming NV are currently developing products that the FDA may determine to be in the same class as our C1-INH product candidate for the acute treatment of HAE. In the event that either of these companies are first to obtain FDA licensure for their product, we could be prevented from obtaining licensure and marketing our C1-INH product candidate for the acute treatment of HAE.

We currently have a very limited sales and marketing organization. If we are unable to establish a direct sales force or we are unable to enter into marketing agreements with third parties in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have a very limited sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market these products directly to health care providers in the United States through our own sales force and enter into distribution agreements with one or more third parties. We will incur significant additional expenses and may need to commit significant additional management resources to promote and sell our products. In the event we are unable to develop our own sales force and collaborate with one or more third parties to sell our product candidates, we may not be able to commercialize our product candidates, which would negatively impact our ability to generate revenue.

If the FDA does not approve our contract manufacturers' facilities, we may be unable to develop or commercialize our product candidates.

We rely on Sanquin to manufacture our product candidates, and currently have no plans to develop our own manufacturing facility. The facilities used by Sanquin to manufacture our product candidates will require approval by the FDA. There can be no assurance that Sanquin will be able to obtain or maintain compliance with the FDA's requirements. We may need to find alternative manufacturing facilities, which would result in significant costs to us as well as a delay of up to several years in obtaining approval for and manufacturing of our product candidates.

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 not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We have an agreement with a third party clinical research organization, or CRO, to implement, provide monitors and manage data for our clinical programs. We and our CRO are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. In the future, if we or our CRO fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials for products in clinical development comply with GCPs. In addition, our clinical trials must be conducted with products produced under current Good Manufacturing Practices, or cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our current or future relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if we sell our products commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We have clinical trial liability insurance that covers our clinical trials with an annual aggregate limit of $5,000,000. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. We believe that we will be able to procure sufficient insurance coverage for our proposed clinical development activities. However, as enrollment in our clinical trials increases and we initiate additional clinical trials, such insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If we are required to pay a product liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product

candidates and, if so, our business and results of operations would be harmed.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight.

If we receive regulatory approval to sell our product candidates, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products. In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

- a change in the labeling statements or withdrawal of FDA or other regulatory approval of the product;
- a change in the way the product is administered; or
- the need to conduct additional clinical trials.

Discovery after approval of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such products' manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part 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, particularly Judson Cooper,

our Chairman and Executive Vice President, and Joshua D. Schein, Ph.D., our Chief Executive Officer. The loss of services of Mr. Cooper or Dr. Schein, or one or more other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

Recruiting and retaining qualified scientific personnel, clinical personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from other companies, universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

We are a small company with 26 employees as of March 1, 2008. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Reimbursement may not be available for our product candidates, including due to legislative or regulatory reform of the healthcare system, which could diminish our sales or affect our ability to sell our products profitably.

C1-INH, if commercialized, is likely to be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if we cannot depend on governmental, private third-party payors and other third-party payors, including Medicare and Medicaid, to defray the cost of C1-INH to the consumer. If these entities refuse to provide coverage and reimbursement with respect to C1-INH or determine to provide an insufficient level of coverage and reimbursement, C1-INH may be too costly for general use, and physicians may not prescribe it. Many third-party payors cover only selected drugs, making drugs that are not preferred by such payor more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Third-party payors may be especially likely to impose these obstacles to coverage for higher-priced drugs, which we anticipate C1-INH to be.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability and worsen our financial condition. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

Since C1-INH will likely be too expensive for most patients to afford without health insurance coverage, if adequate coverage and reimbursement by third-party payors is not available, our ability to successfully commercialize C1-INH may be adversely impacted. Any limitation on the use of C1-INH or any decrease in the price of C1-INH will have a material adverse effect on our ability to achieve profitability. Even where patients have access to insurance, their insurance co-payment amounts may be too expensive for them to afford.

As a result of legislative proposals and the trend towards managed healthcare in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs. Market acceptance and sales of our product candidates will depend on reimbursement policies and healthcare reform measures. The levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products will affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payers. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

Rapid technological change could make our product candidates obsolete.

Biopharmaceutical technologies have undergone rapid and significant change and we expect that they will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. Rapid technological change could make our products obsolete or uneconomical. Our future success will depend not only on our ability to develop our product candidates, but also on our ability to maintain market acceptance against emerging industry developments. We cannot assure prospective investors that we will be able to do so.

Compliance with the Sarbanes-Oxley Act of 2002 will result in increased expenditures.

We are exposed to significant costs and risks associated with complying with increasingly stringent and complex regulation of corporate governance and disclosure standards. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and new SEC regulations require a growing expenditure of management time and external resources. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal controls, and attestations of the effectiveness of our internal controls by our independent auditors. Under current law, the internal controls certification and attestation requirements of Section 404 of the Sarbanes-Oxley are first applicable to us for our fiscal year ending December 31, 2007. As our SEC reporting status has evolved from "small business" issuer to "accelerated filer" we must comply with Section 404 of The Sarbanes-Oxley Act of 2002 and have our independent registered public accounting firm attest to management's assessment of our internal controls over financial reporting. By reason of this reporting status, our compliance costs have substantially increased and a significant portion of management's time has been allocated in order to comply with these rules, especially with respect to compiling the initial comprehensive documentation of our internal controls, and then evaluating and testing the operating effectiveness of our internal controls systems. Any failure by us to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. This process may also require us to hire additional personnel and outside advisory services and will result in significant accounting and legal expenses. We expect to incur significant expense in future periods to comply with regulations pertaining to corporate governance and internal controls as described above.

We have a significant amount of net operating loss and credit carryforwards the use of which may be limited in certain circumstances.

As of December 31, 2007, we have available, for tax purposes, unused net operating loss carryforwards of approximately $20,378,000 that expire from 2023 to 2027. We also have approximately $1,261,000 of research and development credits that expire from 2024 to 2027. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss and credit carryforwards prior to December 4, 2007 and August 23, 2004 is limited due to a cumulative change in ownership of more than 50% that occurred within a three-year period. In the event we achieve profitable operations, any significant limitation on the utilization of net operating loss and credit carryforwards would have the effect of increasing our current tax liability.

Risks related to our intellectual property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling, and offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent position of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the

breadth of claims that may be allowed or enforced in our licensed patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our licensed patents, or for which we are not licensed under our license agreements;
- we or our licensor might not have been the first to make the invention covered by our future pending patent applications, if any, or the pending patent applications and issued patents of our licensors;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications, if any, or one or more of the pending patent applications of our licensor, will not result in issued patents;
- the issued patents of our licensor may not provide us with any competitive advantage, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights or use our technology.

If we pursue litigation to stop someone else from using the inventions claimed in our owned or licensed patents or the patents issuing from a licensed application, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights in these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to cease engaging in activities judged to be covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving invalidity and/or unenforceability is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our licensors' issued patents or patents issued from a licensed application or our licensors' pending applications or that we or our licensors were the first to invent the

technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of inventions in the United States. The cost of these proceedings would be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions. In addition, we have sought to register a number of trademarks in the US and in certain foreign jurisdictions, including the trademarks "Lev Pharma" and "Cinryze". These applications are currently pending and no assurance can be given that registration will be obtainable or if obtained, will be effective to protect our trademarks. Certain third parties, however, have opposed our trademark application for "Lev Pharma" with the U.S. Patent and Trademark Office and with the Community Trade Marks Office of the European Union. We are vigorously contesting these proceedings and do not believe that they will have a material adverse effect on our business, results of operations or financial condition. However, no assurances can be given that such belief will ultimately prove to be accurate, in which case the ultimate resolution of these matters could potentially have a material adverse effect on our business.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Relating to our Securities

As a result of the shares issued in our recent financing transactions, the number of shares of our common stock outstanding has increased substantially and certain purchasers beneficially own significant blocks of our common stock and these shares are generally available for resale in the public market.

Upon the closing of the private placement in October 2006, we issued to a small group of institutional and other accredited investors an aggregate of 32,307,693 shares of common stock, plus warrants to purchase an aggregate of 9,692,308 additional shares of common stock. We also issued warrants to purchase 1,897,057 shares of common stock to registered-broker dealers that assisted us in this transaction. Under the purchase agreement for the private placement, we agreed to file a registration statements with the SEC covering the resale of the all of the shares of common stock issued or to be issued in the private placement, including the shares of common stock issuable upon exercise of the warrants. We have also granted to the purchasers piggyback rights to participate in any company registration, subject to certain limitations. This registration statement was initially declared effective by the SEC on December 11, 2006 and these shares are presently generally available for immediate resale in the public market. In addition, in August 2007 we sold an aggregate of 23,333,333 shares of common stock and warrants to purchase 4,666,667 shares of common stock in a registered direct offering to certain institutional investors. The market price of our common stock could fall due to this increase in the number of shares available for sale in the public market. Further, the issuance of these securities resulted in substantial dilution to stockholders who held our common stock prior to the time of the transactions.

If we are unable to make the scheduled principal and interest payments on the term loan facility or maintain compliance with other debt covenants as defined in the loan and security agreement, we may default on our debt.

In November 2007, we entered into a loan and security agreement for up to $20 million. Upon execution of the agreement, we borrowed an initial amount of $10 million under the agreement. The loan is secured by all of our assets. Under the agreement, we are required to maintain a minimum liquidity level based on the balance of the outstanding advances. As the loan agreement requires our compliance with customary covenants and restriction, it may affect our operations in several ways, including the following:

- A portion of our cash flow from operations will be dedicated to the payment of the principal and interest on our indebtedness;
- Our future cash flow may be insufficient to meet our required principal and interest payments;
- We may need to raise additional capital in order to remain in compliance with the loan covenants; or

- Our ability to enter into certain transactions, incur additional indebtedness and dispose of certain assets may be limited.

Our ability to request additional loans is subject to our ability to maintain a borrowing base in excess of the outstanding aggregate loan amount. Further, if the outstanding loan amount exceeds the borrowing base, then we will be required to prepay an amount equal to such excess, and, if applicable, the lender's total commitment shall be reduced to equal the borrowing base at the time of such mandatory prepayment. The loan is for a term of 36 months and matures on November 1, 2010. Interest on the loan accrues at the rate of 13.5% per annum. Commencing November 1, 2008, we must pay minimum interest payments of 10.5%. We can prepay the outstanding principal and accrued but unpaid interest, subject, however, to making payment of a make-whole premium during the first year and a prepayment fee thereafter, until May 1, 2010. In addition to the conditions above, we may not be able to borrow additional funds under this agreement if we are not able to maintain various negative and financial covenants. Further, events of default are not limited to, but include the following:

- Payment default;
- Covenant default;
- A material adverse change in our business, including the development path for Cinryze™;
- Breach of our agreements with Sanquin; or
- Judgments against us over a certain dollar amount.

In case of an uncured default, the following actions may be taken against us by the lenders:

- All outstanding obligations associated with the term loan facility would be immediately due and payable;
- Any future advancement of credit under the term loan facility would cease;
- Balances and accounts at other financial institutions could be "held" or exclusive control be transferred to the lending institutions; and
- All collateral, as defined in the agreement, could be seized and disposed of.

If shares under our universal shelf registration statement are issued, then the price of our securities may be negatively affected.

We have on file with the SEC a universal shelf registration statement on Form S-3 (Registration No. 333-143196), which provides for the offer, from time to time, of common stock, preferred stock, debt securities and warrants up to an aggregate remaining availability of approximately $35 million, net of financing amounts previously executed under this registration statement. The SEC declared the shelf registration statement effective on June 13, 2007. Subject to market conditions and our capital needs, and so long as we are then eligible to use the registration statements under SEC rules, we may again seek to use any remaining availability under the shelf registration statement by making an offering of securities covered for sale under the registration statement. In addition, we may amend our shelf registration statement or file a new shelf registration statement to increase our potential access to capital. The addition of these securities into the market may be dilutive to existing stockholders and have an adverse effect on the price of our securities.

Market volatility may affect our stock and the value of your investment.

The market prices for securities of biopharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;

- announcements of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States and foreign countries;
- the success of our development efforts to acquire or in-license additional products or product candidates;
- any intellectual property infringement action, or any other litigation, involving us;
- non-issuance of patents on our, or our licensors', pending patent applications, or invalidation of our, or our licensors', patents or other intellectual property rights;
- 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; and
- the loss of any of our key scientific or management personnel.

The occurrence of one or more of these factors may cause our stock price to decline, and you may not be able to resell your shares at or above the price you paid for your shares. In addition, the stock market in general, and the markets for biotechnology and biopharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market conditions may adversely affect the trading price of our common stock.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical stocks have experienced significant stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

The ownership interests of our officers and directors could conflict with the interests of our other stockholders.

As of March 1, 2008, our officers and directors beneficially own approximately 25.7% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

We may be subject to "penny stock" regulations that would limit the trading market for our common stock.

Our common stock is currently listed for trading on the OTC Bulletin Board which is generally considered to be a less efficient market than markets such as Nasdaq or other national exchanges, and which may cause difficulty in obtaining future financing. Further, the SEC has adopted regulations which generally define Penny Stocks to be an equity security that has a market price less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exemptions. As the closing price for our common stock is currently less than $5.00 per share, it may be designated a "Penny Stock." Although we currently satisfy the net worth exemption from the "Penny Stock" definition, no assurance can be given that such exemption will be maintained. As a Penny Stock, our common stock may become subject to Rule 15g-9 under the Exchange Act, or the Penny Stock Rules. This rule imposes additional sales practice requirements on broker-dealers that sell such securities to persons other than established customers and "accredited investors". For transactions covered by Rule 15g-9, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to sale. As a result, this rule may affect the ability of broker-dealers to sell our securities and may affect the ability of purchasers to sell any of our securities in the secondary market. Many brokers have decided not to trade "penny stock" because of the requirements of the Penny Stock Rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. For any transaction involving a penny stock, unless exempt, the rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule prepared by the SEC relating to the penny stock market. Disclosure is also required to be made about sales

commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stock. In the event that we are subject to the Penny Stock Rules for any significant period, there may develop an adverse impact on the market for our securities and investors will find it more difficult to dispose of our securities. Further, for companies whose securities are traded on the OTC Bulletin Board, it is more difficult: (i) to obtain accurate quotations, (ii) to obtain coverage for significant new events because major wire services, such as the Dow Jones News Service, generally do not publish press releases about such companies, and (iii) to obtain needed capital. There can be no assurance that our common stock will continue to qualify for exemption from the penny stock restrictions.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. As of March 3, 2008, there were approximately 69,056,596 shares of restricted common stock outstanding that may be eligible for sale pursuant to Rule 144 under the Securities Act of 1933. Amended Rule 144 provides, that, in general, a person that is not an affiliate of our company that holds restricted securities for a period of six months may sell such shares subject only to our compliance with the current public information requirement until the end of a one year holding period and after one year, these securities may be freely sold without regard to such requirement. Sales of our common stock by certain present stockholders under Rule 144 may, in the future, have a depressive effect on the market price of our securities. In addition, the sale of shares by officers and directors and other affiliated shareholders may also have a depressive effect on the market for our securities.

Because we do not intend to pay dividends, you will benefit from an investment in our common stock only if it appreciates in value.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. The success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

- authorizing the issuance of "blank check" preferred that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

Exercise of outstanding options and warrants will dilute stockholders and could decrease the market price of our common stock.

As of March 3, 2008, we had issued and outstanding options and warrants to purchase an aggregate of 31,960,390 additional shares of common stock. To the extent that these securities are exercised or converted, dilution to our shareholders will occur. The exercise of these securities by the holders may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital. This excludes 4,000,000 shares of unvested restricted stock issued on December 20, 2007.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Currently, we do not have any unresolved comments from the SEC staff with respect to our prior filings.

ITEM 2. DESCRIPTION OF PROPERTY

On December 20, 2006, we entered into a lease for office space at 675 Third Avenue, Suite 2200, New York, NY 10017, for approximately 3,400 square feet to serve as or principal executive offices. This lease commenced in February 2007 and expires in January 2012. Our rent obligation for this lease is $15,556 per month. In addition, in September, 2006, we entered into a twelve month lease for approximately 3,100 square feet of office space in the metropolitan Philadelphia, Pennsylvania area. This lease agreement was amended on August 7, 2007 for an additional one year term. Our rent obligation for this lease is $6,149 per month. We believe that our office space is adequate for our current needs and for the next few years, and we expect that additional facilities will be available in other locations to the extent that we require new or additional space.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not presently a party to any proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations or financial condition, including the administrative proceedings described above under the caption "Intellectual Property – Trademarks".

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITYHOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of 2007.

PART II.

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Principal Market and Market Prices

Our common stock has traded on the OTC Bulletin Board under the symbol "LEVP.OB" since February 18, 2005. From April 10, 2002 to February 17, 2005 our common stock had been quoted on the OTC Bulletin Board under our prior name "Fun City Popcorn, Inc." under the symbol "FNCY."

As of March 1, 2008, there were 560 holders of record. This does not reflect those shares held beneficially or those shares held in "street" name. The table below sets forth the high and low bid prices per share of the common stock for each full quarterly period in the last two fiscal years and the year to date as reported on the OTC Bulletin Board. These prices reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not represent actual transactions. No prediction can be made as to the effect, if any, that future sales of shares of our common stock or the availability of our common stock for future sale will have on the market price of our common stock prevailing from time-to-time.

	High	Low
Year Ended December 31, 2007:		
Fourth quarter	$ 2.00	1.50
Third quarter	$ 1.86	1.21
Second quarter	$ 1.99	1.41
First quarter	$ 1.96	1.25
Year Ended December 31, 2006:		
Fourth quarter	$ 1.36	0.71
Third quarter	$ 0.90	0.43
Second quarter	$ 0.67	0.30
First quarter	$ 0.80	0.60

On March 3, 2008, the last reported sale price for the common stock on the OTC Bulletin Board was $1.14 per share.

Dividend Policy

It is our present policy not to pay cash dividends and to retain future earnings to support our growth. We do not anticipate paying any cash dividends in the foreseeable future.

Recent Issuances of Unregistered Securities

During the fiscal year ended December 31, 2007, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act") except as disclosed in previous SEC filings and as set forth below. Issuances of unregistered equity securities during the current fiscal year are disclosed in Item 9B of this Annual Report.

During the fourth quarter of 2007, we granted 2,165,273 options to employees and a non-executive director outside of our 2004 Omnibus Incentive Compensation Plan. The transactions were exempt from the registration requirements of Section 5 of the Securities Act under Sections 4(2) of the Securities Act. Each option holder agreed that, if the option is exercised, the option holder would purchase his common stock for investment and not for resale to the public. These option awards are exercisable for a seven year term at the fair market value on the date of grant and are subject to time-based vesting conditions.

In December 2007, in connection with entering into amended and restated employment agreements with our Chief Executive Officer and our Chairman, we granted each of them 2,000,000 shares of restricted stock. These restricted stock awards are subject to the following vesting requirements: 50% of the restricted stock shall vest and the restrictions thereon shall lapse on the date that the U.S. Food and Drug Administration approves our biologics license application for our lead product candidate and thereafter 25% of the restricted stock shall vest and the restrictions thereon shall lapse on each of the first and second anniversaries of such approval date. Theses shares were exempt from the registration requirements of Section 5 of the Securities Act under Sections 4(2) of the Securities Act.

Equity Compensation Plan Information

The following table shows information with respect to each equity compensation plan under which our common stock is authorized for issuance as of the fiscal year ended December 31, 2007.

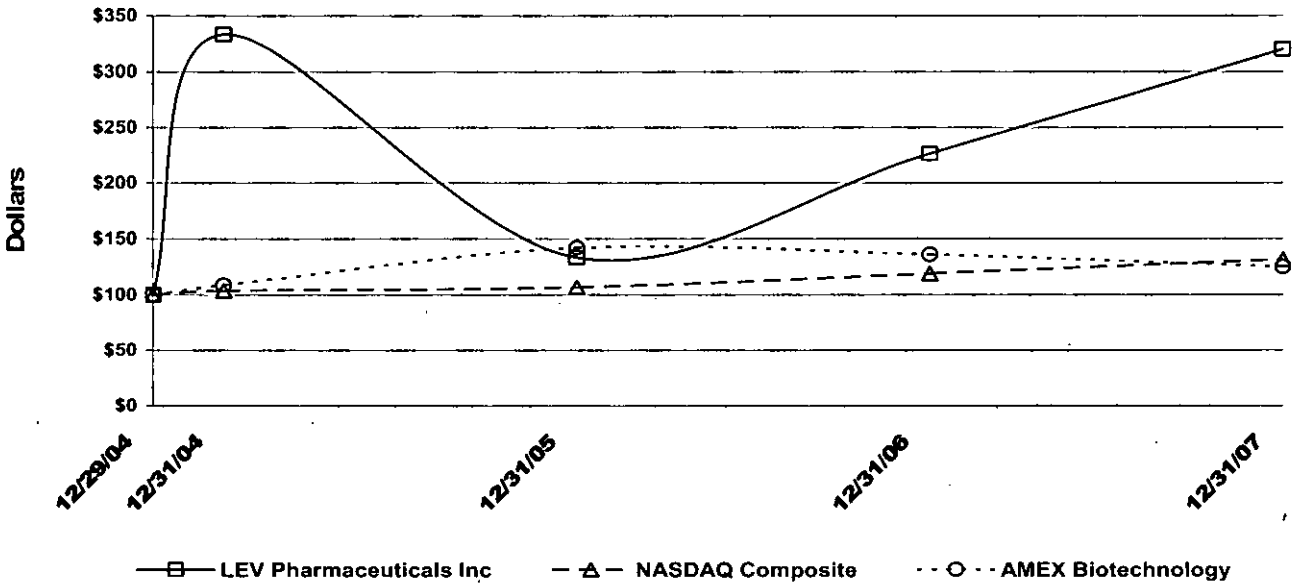
	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	9,984,900		$ 1.00 (1)	15,100
Equity compensation plans not approved by security holders	6,601,614	(2)	$ 1.78	-N/A-
Total	16,586,514		$ 1.31	15,100

(1) The weighted-average exercise price information has been adjusted for the repricing, from $0.85 to $0.30 per share, of options to purchase 2,854,900 shares during 2005, see Note K to the Consolidated Financial Statements.
(2) Represents 436,341 warrants to purchase shares of common stock issued to consultants for services; options to purchase 2,165,273 shares of our common stock issued to certain of our employees outside of our 2004 Omnibus Incentive Compensation Plan; and 4,000,000 shares of restricted common stock issued to Messrs. Cooper and Schein in December 2007 outside of our 2004 Omnibus Incentive Compensation Plan.

Performance Graph

The following Performance Graph and related information shall not be deemed "soliciting material" or "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 (the "Securities Act"), or the Securities Exchange Act of 1934 (the "Exchange Act"), each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The graph below shows a comparison of cumulative total return on our common stock to the cumulative return of the NASDAQ Composite Index and the AMEX Biotechnology Index since December 29, 2004. The performance graph is being shown only from December 29, 2004 because our predecessor had been a non-operating company with very limited trading of its common stock until the December 29, 2004 closing of the merger between Fun City Popcorn, Inc. and Lev, which had been a private company. The comparison assumes that $100 was invested December 29, 2004 in our Common Stock and in each of the foregoing indices. The performance graph assumes reinvestment of dividends, where applicable. The stock performance shown on the graph below is based on historical data and is not indicative of, or intended to forecast, the possible future performance of our common stock.



	12/29/04	12/31/04	12/31/05	12/31/06	12/31/07
Lev Pharmaceuticals Inc	$100.00	$333.33	$133.33	$226.67	$320.00
NASDAQ Composite	100.00	103.55	106.60	119.10	131.45
AMEX Biotechnology	100.00	108.58	142.00	135.97	124.70

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below, which has been derived from our audited consolidated financial statements for the fiscal years 2003-2007. The financial data relating to 2005-2007 should be read in conjunction with Item 7 — "Management's Discussion and Analysis of Financial Condition and Results of Operation" and the accompanying consolidated financial statements and related notes included in this Annual Report. The report of our independent registered public accounting firm included in this Annual Report contains an explanatory paragraph relating to our ability to continue as a going concern, as described in Note B to the consolidated financial statements. The following table sets forth selected consolidated financial data as of and for the years in the five year period ended December 31, 2007. All share and per share amounts have been adjusted to reflect the per share exchange ratio in the Public Company Merger. Historical results are not necessarily indicative of the results to be expected in the future.

	Years Ended December 31,				
	2007	2006	2005	2004	2003 (1)
Consolidated Statements of Operations Data:					
Costs and expenses:					
Research and development	$ 15,379,305	$ 7,167,459	$ 2,368,834	$ 1,126,933	$ 7,000
Merger costs				283,732	
General and administrative	13,110,974	4,835,444	4,110,005	3,262,461	113,171
Loss before other income	$(28,490,279)	$(12,002,903)	$(6,478,839)	$(4,673,126)	$ (120,171)
Other income:					
Interest income	912,962	281,852	181,895	50,912	
Interest expense	(494,643)	(46,438)	(11,412)		(54)
Foreign exchange loss	(9,466)				
Net loss	$(28,081,426)	$(11,767,489)	$(6,308,356)	$(4,622,214)	$ (120,225)
Net loss per share – basic and diluted	$ (0.23)	$ (0.13)	$ (0.08)	$ (0.07)	$ (0.00)
Weighted average shares – basic and diluted	122,955,013	88,235,294	79,624,173	62,384,473	37,164,757

(1) For the period of July 21, 2003 through December 31, 2003. Lev merged with Fun City Popcorn, Inc. on December 29, 2004 and all historical data prior to the merger is that of Lev.

	As of December 31,				
	2007	2006	2005	2004	2003
Consolidated Balance Sheets Data:					(Unaudited)
Cash and cash equivalents	$ 21,910,084	$ 7,887,635	$ 3,482,616	$ 5,544,507	$ 300,409
Working capital	31,688,853	15,191,097	5,295,131	5,523,214	289,775
Total assets	39,348,525	18,572,725	6,393,655	5,873,722	300,409
Long-term debt	13,566,546	1,803,554	316,077		
Accumulated deficit	(51,269,765)	(23,188,339)	(11,420,850)	(5,112,494)	(120,225)
Total stockholders' equity	22,084,248	13,611,972	5,065,793	5,542,324	179,775

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

The following discussion should be read in conjunction with our financial statements and other financial information appearing elsewhere in this Form 10-K. In addition to historical information, the following discussion and other parts of this Form 10-K contain forward-looking information that involves risks and uncertainties.

Forward Looking Statements

We are including the following cautionary statement in this Annual Report on Form 10-K to make applicable and take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for any forward-looking statements made by or on our behalf. Forward looking statements include statements concerning plans, objectives, goals, strategies, future events or performance and underlying assumptions and other statements which are other than statements of historical facts. Certain statements contained herein are forward-looking statements and accordingly involve risks and uncertainties which could cause actual results or outcomes to differ materially from those expressed in good faith forward-looking statements. Our expectations, beliefs and projections are expressed in good faith and are believed by us to have a reasonable basis, including without limitation, management's examination of historical operating trends, data contained in our records and other data available from third parties, but there can be no assurance that management's expectations, beliefs or projections will result or be achieved or accomplished. Any forward-looking statement contained in this document speaks only as of the date on which the statement is made. We undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances that occur after the date on which the statement is made or to reflect the occurrence of unanticipated events.

In addition to other factors and matters discussed elsewhere herein, the following are important factors that in our view, could cause actual results to differ materially from those discussed in the forward-looking statements: the carrying-out of our research and development program for our product candidates, including demonstrating their safety and efficacy at each stage of testing; the timely obtaining of regulatory approvals and patents; the commercialization of our product candidates, at reasonable costs; the ability of our suppliers to continue to provide sufficient supply of products; the ability to compete against products intended for similar use by recognized and well capitalized pharmaceutical companies; our ability to raise capital when needed, and without adverse and highly dilutive consequences to stockholders; and our ability to retain management and obtain additional employees as required. We are also subject to numerous risks relating to our product candidates, manufacturing, regulatory, financial resources, competition and personnel as set forth in the section "Risk Factors" in this report. Except to the extent required by applicable laws or rules, we disclaim any obligations to update any forward looking statements to reflect events or circumstances after the date hereof.

Overview

We are a development stage biopharmaceutical company that was formed in July 2003 to focus on developing and commercializing therapeutic products for the treatment of inflammatory diseases. Our product candidates are based on C1-INH, a human plasma protein that mediates inflammation and is potentially applicable as a treatment for a range of medical indications. We initiated a Phase III clinical trial of our lead product candidate, C1-INH for the acute treatment of HAE, in March 2005. In November 2005, we initiated a Phase III clinical trial of C1-INH for the prophylactic treatment of HAE. In October 2005, we received fast track designation status by the FDA for the treatment of HAE. We are also developing C1-INH for the treatment of selective other diseases and disorders in which inflammation is known or believed to play an underlying role. We have certain rights to C1-INH technology through agreements with Sanquin, an Amsterdam-based not-for-profit organization that provides blood and plasma products and related services, carries out research and provides education, primarily in the Netherlands.

From July 21, 2003 (inception) through December 31, 2007, we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities. We do not currently have any commercial biopharmaceutical products, and do not expect to have a product until mid-2008 at the earliest, subject to FDA approval. As a company that may have limited product revenues, subject to FDA approval, and no profit over the next year, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include clinical trials and regulatory clearance. During 2007, our research and development expenses were $15,379,305.

Research/Product Programs

Hereditary Angioedema

In January 2004, we entered into a distribution and manufacturing services agreement with Sanquin relating to the treatment of HAE. Sanquin currently manufactures and markets a highly purified preparation of C1-INH in Europe and pursuant to the agreement, Sanquin agreed to provide us with C1-INH for use in our clinical trials and for commercial distribution upon regulatory licensure. Pursuant to the agreement, we have distribution rights in Israel and all countries in North, Central and South America, with the exception of the Dutch Overseas Territories, Argentina and Brazil. Under the distribution agreement, it is our responsibility to conduct the Phase III clinical trials of C1-INH for the treatment of HAE and to prepare and file all regulatory applications necessary to register the product candidate. Sanquin agreed to provide us with the technical data and support necessary to assist us in preparing and filing all such regulatory applications. Furthermore, Sanquin agreed to supply C1-INH for our Phase III clinical trials. Upon receipt of FDA approval for our product candidate for the treatment of HAE, upon commercial launch of this product and thereafter during the term of the agreement, Sanquin will supply us with our commercial requirements for C1-INH for the treatment of HAE in each country where we have received regulatory approval. Our purchase of C1-INH from Sanquin is subject to minimum annual purchase requirements upon receipt of FDA approval.

On October 10, 2007, we entered into an amendment, dated as of September 24, 2007, to our distribution and manufacturing services agreement with Sanquin. Pursuant to this amendment, we agreed with Sanquin on the terms regarding a construction project to scale-up the production facilities of Sanquin to be used for the purpose of meeting our anticipated ongoing requirements for the commercial use of its C1-INH product, proposed to be marketed as Cinryze™. Subject to the terms of the final project plan, we would provide Sanquin with a non-interest bearing loan, up to a maximum amount of €7.5 million (approximately US $11.0 million, based on the exchange rate as of December 31, 2007), to finance the construction project. In addition, Sanquin agreed to manufacture our C1-INH product on a toll-manufacturing basis using blood plasma supplied by us. We agreed to purchase a specified amount of product from Sanquin until the scale up is approved by the appropriate regulatory authorities and also agreed to an annual minimum purchase commitment of product of approximately $21.7 million during the term of the agreement commencing in the year in which the scale up is approved in the U.S. for commercial production.

On January 17, 2007, we announced that we have completed patient treatment in the acute portion of a pivotal Phase III clinical trial for our lead product candidate, C1-INH for the treatment of HAE and on March 14, 2007, we announced positive results from our Phase III clinical trial of C1-INH for the acute treatment of HAE. In the acute trial, the protocol-defined primary endpoint was reached, showing a clinically and statistically significant reduction in the time to sustained relief of acute HAE symptoms. Based on the positive results of this trial, we filed a biologics license application, or BLA, with the FDA on July 31, 2007.

On May 31, 2007, we announced that we have completed patient treatment in the second phase of the trial, examining the effectiveness of C1-INH in preventing inflammatory attacks in more severely affected HAE patients and on September 10, 2007 we announced positive results from our Phase III clinical trial of C1-INH for the prophylactic treatment of HAE. In the prophylactic trial, the protocol-defined primary endpoint was achieved, showing a clinically and statistically significant reduction in the number of HAE attacks. Based on the positive results of this study, we amended our BLA filing with the FDA on October 30, 2007. If approved, we intend to commercialize C1-INH ourselves through a specialty sales force in the United States and market this product under the name Cinryze™.

On January 30, 2008, we announced our receipt of a complete response letter from the FDA regarding our BLA for Cinryze™ for the acute and prophylactic treatment of HAE. In our announcement, we stated that the FDA requested information with respect to chemistry, manufacturing and controls, as well as additional analyses of existing efficacy data from the Cinryze™ trials. We are in the process of compiling our response to the information requested by FDA. In addition, we have been advised that the U.S. Food and Drug Administration's Blood Products Advisory Committee, or BPAC, intends to review our BLA for Cinryze on May 2, 2008, for the prophylactic treatment of HAE. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the BLA. Accordingly, there can be no assurance that the outcome of our Phase III trials will be successful or that the results of the trials will support licensure by the FDA.

Acute Myocardial Infarction

We entered into a separate license agreement with Sanquin on January 27, 2004 relating to the treatment of AMI. Under this agreement, we have an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to the use of C1-INH for the treatment of AMI. In connection with the license agreement, we paid Sanquin certain fees and reimbursed Sanquin for certain expenses. In addition, we have an obligation to pay Sanquin royalties on sales of products incorporating the licensed technology.

This second development program is focused on the use of C1-INH in treating AMI. Current treatments for AMI, both surgical and pharmaceutical, are directed at restoring blood flow to heart tissue or preventing further obstruction. Despite a widespread appreciation for the role of inflammation in AMI in both the scientific and medical communities, no presently available treatments directly target the mechanisms of inflammation. Based on preliminary animal and clinical data, we believe that C1-INH may be useful as a treatment for AMI. Based on the rights obtained from Sanquin, we intend to initiate a research program for the development of a genetically engineered or recombinant version of C1-INH to be used in the treatment of AMI.

Merger Transactions

On November 5, 2004, FCP, Lev Sub and Old Lev entered into the Agreement. On December 29, 2004, the Public Company Merger closed and pursuant to the Agreement, Lev Sub merged into Old Lev and the combined entity became a wholly-owned subsidiary of FCP. As a result of the Public Company Merger, FCP issued 5,029,795 shares of common stock and 4,789,433 shares of Series A convertible preferred stock to holders of outstanding Old Lev common stock.

On December 29, 2004, the Board of Directors and stockholders of FCP approved a merger of FCP into a newly formed, wholly-owned subsidiary of FCP incorporated in Delaware. This merger was undertaken to increase the authorized number of shares of common stock to permit the conversion of the Series A preferred stock, to reincorporate FCP in the State of Delaware and to change the name of the company. On February 17, 2005, the Recapitalization Merger closed and the issued and outstanding Series A Preferred Stock of FCP was automatically converted into an aggregate of 66,767,994 shares of common stock which, along with the 4,505,530 shares of FCP common stock outstanding prior to the Public Company Merger and the 5,029,795 shares of common stock issued to the Old Lev stockholders in the Public Company Merger, resulted in a total of 76,303,319 shares of common stock outstanding as of February 17, 2005. As part of the Recapitalization Merger, Old Lev changed its name to Lev Development Corp. and FCP changed its name to Lev Pharmaceuticals, Inc. As a result of these mergers, the stockholders of Old Lev acquired approximately 94% of our outstanding common stock.

The Public Company Merger, which resulted in the stockholders of Old Lev obtaining control of FCP, represents a recapitalization of FCP, or a "reverse merger", rather than a business combination. In connection therewith, Old Lev's historical capital accounts were retroactively adjusted to reflect the equivalent number of shares issued by FCP while Old Lev's historical accumulated deficit was carried forward.

Employment Agreements

New Amended and Restated Executive Employment Agreements

On December 20, 2007, we entered into second amended and restated employment agreements with each of its Chief Executive Officer, Mr. Joshua D. Schein, and its Executive Vice President and Chairman, Mr. Judson Cooper. As used in the following summary, the term "Executive(s)" shall refer to Messrs. Schein and Cooper. In addition to the execution of the amended and restated employment agreements, on December 20, 2007, we also awarded each of the Executives a cash bonus for the 2007 fiscal year of $425,000, which was approved by our Compensation Committee. The amended and restated employment agreements are for an initial term expiring December 31, 2012 and at the end of the initial term renew automatically for additional one year terms unless sooner terminated or not renewed. Under the employment agreements, the Executives will continue to receive a base salary of $425,000; provided, however, that the base salary shall increase to $500,000 effective upon the date on which the U.S. Food and Drug Administration approves our biologics license application for its lead product candidate (the "Approval Date"). In addition, the base salary shall increase at the end of each year of service (commencing at the end of 2007) by the greater of (i) 4% or (ii) a percentage

equal to the increase, if any, in the United States Department of Labor Consumer Price Index (or comparable index, if available) for the New York metropolitan area over the previous 12 months. Commencing in the year in which the Approval Date occurs, the Executives will be entitled to a bonus opportunity within the target range of 75% to 200% of base salary, based on satisfaction of performance targets to be determined by the Compensation Committee. In addition, we granted 2,000,000 shares of restricted common stock to each of the Executives with the following vesting schedule: 50% of the restricted stock shall vest and the restrictions thereon shall lapse on the Approval Date and thereafter 25% of the restricted stock shall vest and the restrictions thereon shall lapse on each of the first and second anniversaries of the Approval Date

Satisfaction of Cash Resources

To date, we have relied solely upon selling equity securities in private placements to generate cash to implement our plan of operations. Based on our current levels of research and development and our business plan, we believe that our existing cash and cash equivalents of $21,910,084 as of December 31, 2007 and borrowings from the term loan will be sufficient to meet our cash requirements for the next six months. This raises substantial doubt about the ability for us to continue as a going concern. We do not have any commercial products available for sale and have not generated significant revenues and there is no assurance that if approval of their products is received that we will be able to generate cash flow to fund operations. As we expect that our cash used in operations will increase significantly over the next several years, we may be required to raise additional capital to complete the development and commercialization of our current product candidates. We will pursue equity and/or debt financing alternatives or other financing in order to raise needed funds. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. In addition, we intend to continue to seek purchasers of the residual plasma derived from our manufacturing process to generate additional cash resources for us. However, we currently do not have any definitive agreements with any third-parties for any such arrangements and no assurances can be given that we will be successful in selling any given quantity of residual plasma on acceptable terms, it at all.

As described elsewhere herein, on November 2, 2007, we entered into a Term Loan Agreement and a Pledge and Security Agreement with the lender executing the Loan Agreement and Mast Capital Management, LLC, as agent for the lender. Under this arrangement, the Lender agreed to provide a term loan facility to us in an aggregate amount of up to $20,000,000 and at closing, the lender funded the Company $10,000,000. In addition, on May 23, 2007 we filed with the SEC a Registration Statement on Form S-3 under the Securities Act, which was declared effective by the SEC on June 13, 2007. This registration statement allows us, from time to time, to offer and sell shares of common stock, preferred stock, warrants to purchase our securities and/or debt securities, up to a maximum aggregate amount of $70 million of such securities. To date, we have issued 23,333,333 shares of common stock and warrants to purchase 4,666,667 additional shares of common stock under this registration statement and we currently have no firm agreements with any third-parties for the sale of additional securities pursuant to this registration statement.

To raise additional funds, we intend to either undertake private placements of our securities, either as a self-offering or with the assistance of registered broker-dealers, or negotiate a private sale of our securities to one or more institutional investors. However, we currently have no firm agreements with any third-parties for any financing arrangements and no assurances can be given that we will be successful in raising additional capital from any proposed financings or that additional financing, if at all available, can be obtained on acceptable terms to us. If we raise additional funds by selling shares of common stock or convertible securities, the ownership of our existing shareholders will be diluted. Further, if additional funds are raised though the issuance of equity or debt securities, such additional securities may have powers, designations, preferences or rights senior to our currently outstanding securities. Any inability to obtain required financing on sufficiently favorable terms could have a material adverse effect on our business, results of operations and financial condition. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. Further, if expenditures required to achieve our plans are greater than projected we will need to raise a greater amount of funds than currently expected.

We have cash commitments through December 31, 2008 of approximately $39.6 million to primarily fund our purchase commitments, the Sanquin upgrade, clinical research programs, leases, long-term debt and executive employment contracts. A significant expense for the Phase III clinical trials is the C1-INH product that we purchase from Sanquin. However, this does not affect our cash position because Sanquin has granted continuing loans to us in the amount of the aggregate purchase price of the C1-INH product. The loan balance as of December 31, 2007 was $4,381,092, net of debt

discount. We fulfilled the loan purchase commitment in August 2007 at which time the aggregate loan amount became fixed. The loans are payable in euros and are subject to foreign exchange fluctuations. Each loan will be forgiven if regulatory approval is obtained. If regulatory approval is not received, then each loan is payable on the earlier of January 16, 2014 or the termination of the Sanquin distribution agreement. We expect to continue to incur costs in continuing our open-label clinical trials and in pursuing regulatory approval of our BLA for the treatment of HAE.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Note B of the notes to our financial statements included in this Form 10-K for the fiscal year ended December 31, 2007. The methods, estimates and judgments we use in applying our most critical accounting policies have a significant impact on the results we report in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate, and different assumptions or estimates about the future could materially change our reported results. We believe the following accounting policies are the most critical to us, in that they are important to the portrayal of our financial statements and they require our most difficult, subjective or complex judgments in the preparation of our financial statements.

Research and development costs

We expense all research and development costs as incurred for which there is no alternative future use. Such expenses include licensing fees and costs associated with planning and conducting clinical trials.

Income taxes

We account for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS No. 109"). SFAS No. 109 requires that we recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. We record an estimated valuation allowance on our deferred tax assets if it is not more than likely that these deferred tax assets will be realized.

We account for uncertain tax positions in accordance with FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") an interpretation of FASB Statement No. 109 (SFAS 109). The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations of and guidance surrounding income tax laws and regulations change over time. As such, changes in our subjective assumptions and judgments can materially affect amounts recognized in the consolidated balance sheets and statements of operations.

Equity-based compensation

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standard No. 123(R), "Share Based Payment" ("SFAS No. 123(R)"), which requires all stock-based payments, including grants of stock options, to be recognized in the Statement of Operations as compensation expense, based on their fair values on the grant date. Under SFAS No.123(R), the estimated fair value of options granted are recognized as compensation expense over the option-vesting period. The Company adopted SFAS No. 123(R), using the modified-prospective-transition method, in which compensation expense is recognized beginning with the effective date of the adoption for all stock-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption but not vested on the date of adoption based upon the grant date fair value estimated in accordance with the original provisions of SFAS No. 123.

Repricing of Warrants and Options

Following consummation of the merger transactions under the Agreement, our Board of Directors in May 2005 determined that the basis for the exchange of warrants and options to purchase common stock of Old Lev that were outstanding prior to the mergers for warrants and options to purchase our common stock after the mergers should be changed. Though the number of shares issuable upon exercise of these warrants and options was increased, the parties to the mergers did not proportionately reduce the exercise price of these warrants and options to account for the increase in the number of shares outstanding after the mergers. The reduced exercise price of these warrants and options was calculated by multiplying the number of shares issuable upon exercise of these warrants and options prior to the mergers times the relevant exercise price, and then dividing that dollar amount by the new number of shares issuable upon exercise of these warrants and options after the mergers.

Prior to the mergers, warrants to purchase 66,667 and 39,000 shares of common stock were outstanding with exercise prices of $0.10 and $0.85 per share, respectively. After the mergers, pursuant to the exchange ratio in the Agreement, warrants to purchase 190,327 and 111,341 shares of common stock were outstanding with exercise prices of $0.10 and $0.85 per share, respectively. The Board believed this was unfair to the holders of the warrants and made a determination to treat the warrant holders on the same basis as the holders of common stock of Old Lev. Accordingly, in May 2005, the exercise price of outstanding warrants to purchase 190,327 shares was reduced from $0.10 to $0.04 per share, and the exercise price of other outstanding warrants to purchase 111,341 shares was reduced from $0.85 to $0.30 per share. At the date of this repricing, we recognized a charge to operations of approximately $28,000 for the incremental value of these warrants based upon the Black Scholes option pricing model. Prior to the mergers, stock options to purchase 500,000 shares of common stock at an exercise price of $0.85 per share were held by each of Joshua D. Schein, Ph.D., our Chief Executive Officer, and by Judson Cooper, our Chairman. After the mergers, pursuant to the exchange ratio in the Agreement, each person's options were converted into options to purchase 1,427,450 shares of common stock with an exercise price of $0.85 per share (an aggregate of 2,854,900 shares). In May 2005, in addition to repricing the warrants, the Board further determined, subject to obtaining stockholder approval at our next annual meeting, to reduce the exercise price of these options from $0.85 to $0.30 per share. The Board made the determination to seek stockholder approval because it believed that stockholder approval was necessary to reduce the exercise price of such options under the terms of our 2004 Omnibus Incentive Compensation Plan. In addition, the Board believed that the repricing of these options should be subject to stockholder approval because the reduction in exercise price of the stock options directly benefits our Chief Executive Officer and Chairman. However, it should be noted that our Chief Executive Officer and Chairman are also principal stockholders who voted on this proposal. The stockholders approved this repricing at the annual meeting held on December 12, 2005. Messrs. Schein and Cooper each own options to purchase 1,427,450 shares of common stock at an exercise price of $0.30 per share as opposed to the prior exercise price of $0.85 per share. If they exercise all of these options, Messrs. Schein and Cooper would realize a cash savings of, and the proceeds received by the Company would be reduced by, $785,098 for each of them. A charge of $1,427,450 was recorded to our Consolidated Statement of Operations based upon our stock price when our stockholders approved the repricing at the stockholders' meeting and subsequent changes to our stock price through December 31, 2005. These charges ceased upon the adoption of SFAS 123R on January 1, 2006.

The fair value of warrants granted to non-employees for financing or services are included in the financial statements and expensed over the life of the services performed. Warrants issued in connection with services or financings were valued at the grant date using the Black Scholes option pricing model. The amounts recorded for the years ended December 31, 2006 and December 31, 2005 were $192,822 and $10,825, respectively.

Recent Accounting Pronouncements

On September 15, 2006 the Financial Accounting Standards Board ("FASB") issued Statement No. 157, *Fair Value Measurements*. The Statement provides guidance for using fair value to measure assets and liabilities. This Statement references fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The Statement applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The Statement does not expand the use of fair value in any new circumstances. It is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The adoption of SFAS No. 157 is not expected to have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115" (SFAS 159), which permits entities to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective as of the beginning of fiscal years after November 15, 2007. We are currently evaluating the impact that SFAS 159 will have on our consolidated financial position, results of operations, and cash flows as of its adoption in 2008.

In December 2007, the SEC issued SAB 110, codified as part of SAB Topic 14.D.2, "Share-Based Payment: Certain Assumptions Used in Valuation Methods - Expected Term." SAB 110 permits companies, under certain circumstances, to continue to use the simplified method when calculating the expected term of "plain vanilla" share options. Originally, the simplified method was due to expire on December 31, 2007. A company may use the simplified method if it concludes that it is not reasonable to base its estimate of expected term on its experience with exercising historical share options. The effective date for SAB 110 is January 1, 2008. Management is in the process of assessing whether the Company will continue to use the simplified method for stock option grants after January 1, 2008.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) ("SFAS 141R"), "Business Combinations" and SFAS No. 160 ("SFAS 160"), "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulleting No. 51." SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interest and classified as a component of equity. SFAS 141R and SFAS 160 are effective beginning the first fiscal quarter of 2009. Early adoption is not permitted. The Company does not expect the adoption of either SFAS 141R or SFAS 160 will have a material impact on its statements of financial position, results of operations and cash flows.

Results of Operations

Year Ended December 31, 2007 as compared to Year Ended December 31, 2006

We had no revenues during the year ended December 31, 2007 because we do not have any commercial biopharmaceutical products.

Research and development expenses for the years ended December 31, 2007 and December 31, 2006 were $15,379,305 and $7,167,459, respectively. The increase of $8,211,846 is primarily due to the purchase of plasma and the manufacture of C1-INH, our lead product candidate, to support our Phase III clinical trials for the acute and prophylactic treatment of HAE, offset by $1,054,084 of sales of residual plasma resulting from our manufacturing process and treated as a cost-recovery. Included in research and development expense for the year ended December 31, 2007 is employee stock option expense of $173,227. For the year ended December 31, 2006, the Company entered an employment contract with its Vice President of Regulatory Affairs and Product Development for $200,000 plus bonus and options to purchase 500,000 shares of our common stock, see Note J[5] to our Consolidated Financial Statements.

General and administrative expenses were $13,110,974 and $4,835,444 for the years ended December 31, 2007 and December 31, 2006, respectively. The increase of $8,275,530 was due to increased salaries and benefits, marketing, professional fees, travel and stock option expense. Employee stock option expense for the years ended December 31, 2007 and 2006 included in general and administrative expense were $2,143,309 and $281,233. During the year ended 2007, we hired Dov Elefant as our Corporate Controller pursuant to the terms of an offer letter and during the year ended December 31, 2006, our CFO and Vice President of Sales and Marketing entered into employment contracts for annual salaries of $415,000 in the aggregate, plus bonus and options to purchase 725,000 shares of our common stock, see Note J[5] to our Consolidated Financial Statement.

Interest income for the year ended December 31, 2007 and December 31, 2006 was $912,962 and $281,852, respectively. The increase of $631,110 is attributable to obtaining a higher rate of interest and having more cash to invest.

Interest expense for the year ended December 31, 2007 and December 31, 2006 was $494,643 and $46,438, respectively. The increase of $448,205 is primarily attributable to an increase in 2007 of $152,690 of imputed interest attributable to

non-interest bearing loans from Sanquin, our supplier of C1-INH product, and accrued interest of $222,471 and , amortization of debt discount and deferred financing costs of $72,641 attributable to the term loan payable.

Due to the factors mentioned above, the net loss for the year ended December 31, 2007 was $28,081,426 or $0.23 per common share, basic and diluted, based upon weighted average shares outstanding of 122,955,013 shares as compared to a loss for the year ended December 31, 2006 of $11,767,489 or $0.13 per common share, basic and diluted, based upon weighted average shares outstanding of 88,235,294.

Year Ended December 31, 2006 as compared to Year Ended December 31, 2005

We had no revenues during the year ended December 31, 2006 because we do not have any commercial biopharmaceutical products.

Research and development expenses for the years ended December 31, 2006 and December 31, 2005 were $7,167,459 and $2,368,834, respectively. The increase of $4,798,625 is primarily due to the progress of our Phase III clinical trials of our lead product candidate, C1-INH for the acute treatment of HAE, which commenced in March 2005. In addition, in November 2005, we initiated a Phase III clinical trial of C1-INH for the prophylactic treatment of HAE. Included in research and development expense for the year ended December 31, 2006 is employee stock option expense of $176,118. In addition, the Company issued warrants for service with a fair market value of $134,419 and recorded an additional expense of $194,000 as disclosed in Note I [2] to our Consolidated Financial Statement. For the year ended December 31, 2006, the Company entered an employment contract with its Vice President of Regulatory Affairs and Product Development for $200,000 plus bonus and options to purchase 500,000 shares of our common stock, see Note H[4] to our Consolidated Financial Statements.

General and administrative expenses were $4,835,444 and $4,110,005 for the years ended December 31, 2006 and December 31, 2005, respectively. The increase of $725,439 was due to increased salaries and benefits, marketing, professional fees, travel and stock option expense. Employee stock option expense for the year December 31, 2006 included in general and administrative expense was $281,233. For the year ended December 31, 2005, we recorded non-cash compensation expense of $1,427,450 for option repricing for the benefit of our Chairman and our CEO that was approved by our stockholders, see Note K to our Consolidated Financial Statements. During the year ended December 31, 2006, our CFO and Vice President of Sales and Marketing entered into employment contracts for annual salaries of $415,000 in the aggregate, plus bonus and options to purchase 725,000 shares of our common stock, see Note H [4] to our Consolidated Financial Statement.

Interest income for the year ended December 31, 2006 and December 31, 2005 was $281,852 and $181,895, respectively. The increase of $99,957 is attributable to obtaining a higher rate of interest and having more cash to invest.

Interest expense for the year ended December 31, 2006 and December 31, 2005 was $46,438 and $11,412, respectively. The increase of $35,026 represents imputed interest attributable to non-interest bearing loans from Sanquin, our supplier of C1-INH product.

Due to the factors mentioned above, the net loss for the year ended December 31, 2006 was $11,767,489 or $0.13 per common share, basic and diluted, based upon weighted average shares outstanding of 88,235,294 shares as compared to a loss for the year ended December 31, 2005 of $6,308,356 or $0.08 per common share, basic and diluted, based upon weighted average shares outstanding of 79,624,173.

Liquidity and Capital Resources

As of December 31, 2007, we had cash and cash equivalents of $21,910,084 and working capital of $31,688,853. Net cash used in operations was $35,097,916 for the year ended December 31, 2007 and was primarily due to our loss of $28,081,426 in addition to purchases of inventory of $10,645,129 and an increase to prepaid expenses and other assets of $2,354,131 primarily for funding of advance purchases for inventory. The operating loss was partially offset by non cash expenses of $5,458,661 primarily related to stock-based compensation related to employee stock options, purchases of C1-INH product and amortization of debt discount. Pursuant to the Sanquin loan agreement, purchases made during our Phase III clinical trials are added to our loan and we are not required to make any principal payments. The loan balance, net of

debt discount as of December 31, 2007 was $4,381,092 and will be forgiven when regulatory approval from the FDA is received. If we do not receive regulatory approval, then the loan is repayable on the earlier of January 16, 2014, or the termination of the Agreement. The loan does not bear interest and we impute interest using the effective interest rate method. For the year ended December 31, 2007, net cash provided by investing activities was $6,375,374 resulting from the sale of investments of $10,000,000 offset by the purchase of fixed assets for $200,405 and a loan receivable of $3,424,221. Cash provided by financing activities for the year ended December 31, 2007 was $42,744,991 resulting from $32,405,549 of net proceeds from the sale of common stock and warrants, $10,000,000 of gross proceeds from a term loan and $548,955 resulting from proceeds from the exercise of warrants, offset by $209,513 of the term loan financing costs.

Our consolidated financial statements have been presented on the basis that we are a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business. We have limited capital resources and have an accumulated deficit of $51,269,765 since inception and have had negative cash flows from operations since inception. These losses have resulted principally from costs incurred in research and development activities, including acquisition of technology rights and general and administrative expenses. We have cash commitments of $39.6 million through December 31, 2008. We expect to incur additional operating losses until such time as we generate sufficient revenue to offset expenses, and we may never achieve profitable operations. As a development stage enterprise, our primary efforts, to date, have been devoted to conducting research and development, raising capital, forming collaborations and recruiting staff and our capital resources are focused on the clinical development and regulatory approval of C1-INH for the treatment of HAE. To date, we have relied solely upon selling equity and debt securities to generate cash to implement our plan of operations. Based on our current levels of research and development and our business plan, we believe that our existing cash and cash equivalents of $21,910,084 as of December 31, 2007 plus subsequent borrowings discussed below will be sufficient to meet our cash requirements for the next six months. This raises substantial doubt about the ability for us to continue as a going concern. We do not have any commercial products available for sale and have not generated revenues and there is no assurance that if approval of their products is received that we will be able to generate cash flow to fund operations. As we expect that our cash used in operations will increase significantly over the next several years, we may be required to raise additional capital to complete the development and commercialization of our current product candidates. We will pursue equity and/or debt financing alternatives or other financing in order to raise needed funds. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. In addition, we intend to continue to seek purchasers of the residual plasma derived from our manufacturing process to generate additional cash resources for us. However, we currently do not have any definitive agreements with any third-parties for any such arrangements and no assurances can be given that we will be successful in selling any given quantity of residual plasma on acceptable terms, if at all.

The primary sources of our working capital have been equity financings and the establishment of our loan facility. On May 23, 2007, we filed with the SEC a Registration Statement on Form S-3 under the Securities Act, which was declared effective by the SEC on June 13, 2007. This registration statement allows us, from time to time, to offer and sell shares of common stock, preferred stock, warrants to purchase our securities and/or debt securities, up to a maximum aggregate amount of $70 million of such securities. On August 17, 2007, we closed on a registered direct sale to certain institutions of an aggregate of units consisting of 23,333,333 shares of our common stock and warrants to purchase up to an aggregate of 4,666,667 shares of our common stock for aggregate proceeds of $35.0 million. The warrants are exercisable at any time until five years from the closing date at a price of $1.86. We have been using the net proceeds from this transaction of approximately $32.4 million for continued funding of our clinical trials, additional research and development efforts, and general working capital purposes. We paid approximately $2.6 million in total commissions and expenses to investment bankers engaged to assist us in the financing. We currently have no firm agreements with any third-parties for the sale of additional securities pursuant to this registration statement.

On November 2, 2007, we entered into a Term Loan Agreement and a Pledge and Security Agreement with Mast Credit Opportunities I Master Fund, Ltd., as the lender, and Mast Capital Management, LLC, as agent for the lender. Under this arrangement, the lender agreed to provide a term loan facility to us in an aggregate amount of up to $20,000,000, subject to the further terms and conditions of the Loan Agreement. The loan is secured by a first priority lien on all of our assets. At the initial closing, we received an initial loan of $10,000,000. The loan proceeds will be used to finance the cost of additional plasma purchases. The loan is for a term of 36 months and matures on November 1, 2010. Interest on the loan accrues at the rate of 13.5% per annum. We may request additional term loan advances in amounts not less than $1,000,000 each during the twelve month period from the closing date. Our ability to request additional loans is subject to our maintaining (i) a borrowing base in excess of the outstanding aggregate loan amount and (ii) compliance with the

covenants and conditions of the loan. Further, if the outstanding loan amount exceeds the borrowing base, then we will be required to prepay an amount equal to such excess, and, if applicable, the lender's total commitment shall be reduced to equal the borrowing base at the time of such mandatory prepayment.

The Loan Agreement allows us to prepay the outstanding principal amount and all accrued but unpaid interest, subject to payment of a make-whole premium during the first year following the closing and a prepayment fee thereafter, until May 1, 2010. The Loan Agreement requires compliance with customary covenants and restrictions on our ability to, among other things, dispose of certain assets, engage in certain transactions, incur indebtedness and pay dividends. The Loan Agreement also provides for customary events of default following which, the lender may, at its option, accelerate the amounts outstanding under the Loan Agreement. In connection with the Loan Agreement, we issued to the Lender warrants to purchase an aggregate of 900,000 shares of our common stock. The warrants are for a term of three years and have an exercise price of $1.6576 per share, which is the volume weighted average price per share of our common stock for the thirty trading days immediately preceding the closing. The warrants were issued in reliance on the Section 4(2) exemption from the registration requirements of the Securities Act of 1933, as amended. We also entered into a registration rights agreement with the lender pursuant to which we agreed to file a registration statement with the Securities and Commission covering the resale of the shares of common stock which may be issued upon exercise of the warrants upon the demand of the holders of a majority of the warrants. In consideration for services provided on behalf of the Company in connection with the consummation of the transactions contemplated by the Secured Financing Agreements, the Company paid a fee of 1% of the amounts borrowed under the Loan Agreement to Mr. Richard Stone, who is the beneficial owner of greater than 5% of the Company's outstanding common stock.

On February 11, 2008, the lender, agent for the lender and two affiliated individuals filed a Schedule 13G with the Securities and Exchange Commission reporting that as of January 30, 2008, such persons were the beneficial owner of greater than 5.0% of our common stock. Accordingly, in the event that we elect to increase our borrowings under this loan arrangement, such transaction would be reviewed by the audit committee of our board of directors in accordance with our procedures for reviewing related party transactions.

In October 2006, we received net proceeds of $19,584,745 in a private placement, net of issuance costs of $1,415,255 from the sale of 32,307,693 shares of common stock at $0.61 per share and five year warrants to purchase 9,692,308 shares of common from stock at an exercise price of $0.84 per share. The Company issued 1,698,538 and 198,519 warrants to purchase common stock to registered broker-dealers that assisted us in the financings (the "Agent Warrants"). The Agent Warrants are exercisable at $0.84 per share and $1.18 per share and expire five years from the date of issue. We paid $1,279,593 to the placement agent and to the registered broker dealer.

In the May 2005 private placement, we received net proceeds of approximately $4,365,100 from the sale of 100.9 units. Each unit was sold at a price of $50,000 and consisted of 50,000 shares of common stock and a five-year warrant to purchase 25,000 shares of common stock at an exercise price of $1.35 per share. We issued an aggregate of 5,044,774 shares of common stock and warrants to purchase 2,522,387 shares of common stock to investors in this private placement. We paid $454,030 to the placement agent and issued warrants to the placement agent to purchase 681,044 shares of common stock. The placement agent warrants are exercisable at $1.35 per share and expire in May 2010.

In February and March 2004, we received proceeds of $7,968,495 in a private placement, net of issuance costs of $51,465, from the sale of 3,425,879 shares of common stock at $0.26 per share and from the sale of 23,913,848 shares of common stock at $0.30 per share, respectively. In December 2003, we received proceeds in a private placement of $300,000 from the sale of 1,141,960 shares of common stock at $0.27 per share.

To raise additional funds, we intend to either undertake private placements or registered offerings of our securities, either as a self-offering or with the assistance of registered broker-dealers, or negotiate a private sale of our securities to one or more institutional investors. However, we currently have no firm agreements with any third-parties for any financing arrangements and no assurances can be given that we will be successful in raising additional capital from any proposed financings. There can be no assurance that additional financing, if at all available, can be obtained on terms acceptable to us. If we raise additional funds by selling shares of common stock or convertible securities, the ownership of our existing shareholders will be diluted. Further, if additional funds are raised through the issuance of equity or debt securities, such additional securities may have powers, designations, preferences or rights senior to our currently outstanding securities. Any inability to obtain required financing on sufficiently favorable terms could have a material adverse effect on our

business, results of operations and financial condition. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. Further, if expenditures required to achieve our plans are greater than projected or if revenues are less than, or are generated more slowly than, projected, we will need to raise a greater amount of funds than currently expected.

We expect our cash requirements for operating activities will increase due to the following future activities:

- Conduct commercialization activities in support of our product candidates, including development of market plans and regional sales and marketing capabilities;
- Conduct clinical programs, including clinical trials to support regulatory submissions of our product candidates;
- Maintain, protect and expand our intellectual property;
- Develop expanded internal infrastructure; and
- Hire additional personnel.

Effects of Inflation

Our assets are primarily monetary, consisting of cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Contractual Obligations and Commitments

The following is a summary of our significant contractual cash obligations for the periods indicated that existed as of December 31, 2007.

	Total	Less than 1 year	1 - 2 years	3 - 5 years	More than 5 years
Office lease	$908,533	$245,124	$199,347	$464,063	$0
CRO contract	567,437	567,437	0	0	0
Executive employment contracts	5,413,632	1,278,603	1,078,360	3,056,669	0
Plasma contracts	51,789,857	14,058,144	12,225,000	25,506,713	0
Sanquin facility upgrade	7,955,807	7,955,807	0	0	0
Sanquin purchases (a)	19,149,389	15,084,323	4,065,066	0	0
Long-term debt	15,036,990	204,946	1,328,696	13,503,348	0
Research and development contract	234,000	234,000	0	0	0
Total obligations	$101,055,646	$39,628,384	$18,896,469	$42,530,793	$ 0

(a) prior to approval of scale up

Our major contractual obligations relate to purchase commitments, long-term debt, Sanquin facility upgrade and compensation under employment contracts. We expect to devote substantial resources to continue our research and development efforts, to expand our product pipeline and to support our product candidates as they move forward in the clinical development process. Our funding requirements will depend on numerous factors, including:

- the scope and results of our clinical trials;
- advancement of other product candidates into development;
- potential acquisition or in-licensing of other product candidates, commercial products or technologies;
- the timing of, and the costs involved in, obtaining regulatory approvals;

- , the cost of manufacturing activities for product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation; and
- our ability to establish and maintain additional collaborative arrangements.

We expect product development costs to increase in the future as more of our product candidates enter clinical trials. In addition, we may be obligated to make milestone payments on certain of our product candidates as they progress through the clinical trial process. The duration and cost of clinical trials may vary significantly over the life of a particular project as a result of, among other things, the following factors:

- the length of time required to recruit qualified patients for clinical trials;
- the duration of patient dosing and follow-up in light of trial results;
- the number of clinical sites required for trials; and
- the number of patients that ultimately participate.

During our 2006 fiscal year we entered into employment agreements with our Chief Financial Officer, Douglas J. Beck, and Jason Bablak, who serves as our Vice President, Regulatory Affairs and Product Development. In January 2007, we entered into amended and restated employment agreements with our Chairman, Judson Cooper and our Chief Executive Officer, Joshua Schein and further modified those agreements in December 2007. In March 2007 we hired Dov Elefant as our Corporate Controller pursuant to the terms of an offer letter (see Note J to our audited consolidated financial statements).

On June 1, 2007 we exercised an option to extend the Sanquin distribution agreement. Our distribution agreement with Sanquin terminates on December 31, 2010, unless extended by us for up to a three-year period or by mutual agreement of the parties prior to its expiration. On October 10, 2007, we entered into an amendment, dated as of September 24, 2007, to our Distribution and Manufacturing Services Agreement with Sanquin. Pursuant to the amendment, we agreed with Sanquin on the terms of a construction project to scale-up the production facilities of Sanquin to be used for the purpose of meeting our anticipated ongoing requirements for the commercial use of our C1-INH product to be marketed as Cinryze™. Pursuant to the terms and conditions of the amendment, we will develop a project plan for the construction to the production facilities with Sanquin. Subject to the terms of the final project plan, we would provide Sanquin with a non-interest bearing loan, up to a maximum amount of €7.5 million (approximately US $11.0 million, based on the exchange rate as of December 31, 2007), to finance the construction project. This loan will be due July 1, 2014 and Sanquin agreed to repay the principal amount of the loan by providing us with a discount to the per unit purchase price of Cinryze™. The remaining cash commitment is approximately $8 million.

Pursuant to the amendment, Sanquin shall manufacture C1-INH product for us on a toll-manufacturing basis using blood plasma supplied by us. We agreed to purchase a specified amount of such product from Sanquin totaling approximately $19.1 million until the scale up is approved by the appropriate regulatory authorities, which we expect to occur during 2009. In addition, we agreed to an annual minimum purchase commitment of product of approximately $21.7 million during the term of the agreement commencing in the year in which the scale up is approved in the U.S. for commercial production. We agreed to negotiate in good faith to modify these requirements in the event that regulatory approval for commercial release of the Cinryze™ in the U.S. does not occur by March 31, 2008. Our contractual purchase commitments are subject to annual adjustments based on market conditions and do not include the cost of storage, handling and testing services that Sanquin will provide for us.

On July 19, 2007, we entered into an agreement, for the purchase and sale of plasma with DCI Management Group, LLC (the "DCI Agreement") pursuant to which we will purchase quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin. Under the DCI Agreement, the supplier agreed to sell us specified annual quantities of plasma in accordance with applicable good manufacturing practices. We are committed to purchase $13,950,000 of product for 2008. Thereafter we expect our annual purchase commitment to be between $12.2 million and $12.9 million for the balance of the term of the DCI Agreement. Our contractual purchase commitments are subject to annual percentage increases based on market conditions. We anticipate our total commitment under this DCI Agreement to be approximately $51.7 million. In addition, we have an obligation of approximately $108,000 to purchase additional plasma from another supplier.

In connection with the license agreement with Sanquin for the treatment of AMI we are required to create a comprehensive research plan for the commercial exploitation of the licensed technology. We continue to work with Sanquin on the design of the research plan. We committed a minimum of $125,000 per annum during the first three years following the execution of the license agreement toward research on the licensed technology conducted by Sanquin and by other parties. To date, we have funded approximately $141,000 to third parties engaged in this research. We also have an obligation to pay Sanquin royalties on sales of products incorporating the technology.

As described in greater detail above, on November 2, 2007, we entered into a Term Loan Agreement dated as of November 2, 2007 and a Pledge and Security Agreement of the same date, with the lender executing the Term Loan Agreement and Mast Capital Management, LLC, as agent for the lender. The loan is for a term of 36 months and matures on November 1, 2010. Interest on the loan accrues at the rate of 13.5% per annum. Commencing November 1, 2008, we must pay minimum cash interest payments of 10.5% and an additional 3% accrues through the term of the loan. As of December 31, 2007, the principal balance of the loan outstanding was $10,000,000 with accrued interest owed of $222,471 net of debt discount of $1,037,017.

On March 2, 2005, we entered into a CRO services agreement with INC Research which governs INC Research's provision of services in connection with the support of clinical investigation and management and/or research of our Phase III clinical trial. We entered into a separate services agreement with INC Research in September 2006 which governs INC Research's provision of additional services in connection with our Phase III clinical trials and activities related to the commercialization of our product candidates. The services provided by INC Research pursuant to both contractual arrangements are on a work-order basis and we are invoiced on a time and materials basis. We have the right to terminate both agreements, and any pending work-order, with prior notice and without cause. As of December 31, 2007, we have estimated that we will pay INC Research approximately $567,000 for its services under both agreements in 2008. However, due to the variability associated with the conduct of clinical trials, we are unable to estimate with certainty the future costs we will incur under our CRO agreement. We anticipate that these costs will increase significantly above our current estimates if we expand the clinical trials.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2007 with the exception of the lease of our office spaces and copiers.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk Related to Interest Rates and Foreign Currency

We are exposed to market risks related to changes in interest rates and foreign currency exchange rates as described below. We do not have any derivative financial instruments.

Interest Rate Risk

As of December 31, 2007, our cash included approximately $20,182,464 of money market securities. Due to the short term duration of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

Foreign Currency Exchange Risk

We have no revenues and, as a result, we have no exposure to foreign currency exchange risk with respect to revenues. A portion of our expenses, loans payable and loan receivable are payable or denominated in foreign currency. We do not use forward exchange contracts to hedge exposures denominated in foreign currencies or any other derivative financial instruments for trading or speculative purposes. The effect of an immediate 10% change in exchange rates would result in additional cash expenditures of approximately $1,508,000 related to our annual manufacturing costs, additional cash expenditures of approximately $796,000 related to the Sanquin facility upgrade and additional expenses of approximately $625,000 related to our loan payable to Sanquin offset by a gain of approximately $341,000 related to our loan receivable. These changes would have a material impact on our future operating results or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

The full text of our audited consolidated financial statements for the year ended December 31, 2007 and for the period July 21, 2003 (inception) to December 31, 2007 begins on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) under the Exchange Act) as of the end of the period covered by this report, have concluded that, based on the evaluation of these controls and procedures, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

Management's Annual Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based upon the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, our management concluded that our internal control over financial reporting is effective as of December 31, 2007.

Report of the Independent Registered Public Accounting Firm. Eisner LLP, our independent registered public accounting firm, has audited the consolidated financial statements for 2007 included in this Annual Report on Form 10-K and, as part of their audit, has issued their report, set forth at page F-3 of our consolidated financial statements, on the effectiveness of our internal control over financial reporting.

Changes in Internal Controls. There has not been any change in our internal control over financial reporting during our quarter ended December 31, 2007, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We do not expect that internal controls over financial reporting will prevent all errors or all instances of fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within its company have been detected. These inherent limitations include the realities that judgments in decision-

making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and any design may not succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

During the first quarter of 2008, we issued 578,954 shares of our common stock upon exercise of outstanding warrants. These exercises were effected in reliance on Section 4(2) of the Securities Act of 1933, as amended.

PART III.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Portions of the response to this item are incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors—Nominees for Director", "Section 16(a) Beneficial Ownership Reporting Compliance", and "Election of Directors—Board and Committee Matters" in the Company's Definitive Proxy Statement relating to the 2008 Annual Meeting of Stockholders (the "Proxy Statement"). In addition, the information concerning our corporate governance required by this Item will be set forth in our Proxy Statement, to be filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated by reference to our Proxy Statement. The information concerning our executive officers required by this Item is incorporated by reference herein to the section of this Annual Report in Part I entitled "Executive Officers of the Registrant".

Our Board of Directors has adopted a code of business conduct and ethics that applies to our principal executive officers, principal financial officer, and controller, as well as all other employees. A copy of this code of business conduct and ethics has been posted on our Internet website at *www.levpharma.com* under the "corporate governance" section. In addition, hard copies can be obtained free of charge through our investor relations department. Any amendments to, or waivers from, a provision of our code of ethics that applies to our principal executive officer, principal financial officer, controller, or persons performing similar functions and that relate to any element of the code of ethics enumerated in paragraph (b) of Item 406 of Regulation S-K shall be disclosed by posting such information on our website.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated herein by reference from the discussion responsive thereto under the following captions in the Proxy Statement: "Director Compensation," "Executive Compensation" and "Compensation Committee Interlocks and Insider Participation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The response to this item is incorporated herein by reference in part from the discussion responsive thereto under the caption "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated herein by reference from the discussion responsive thereto under the caption "Certain Relationships and Related Transactions" in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated herein by reference from the discussion responsive thereto under the captions "Election of Directors—Board and Committee Matters" and "Information Concerning Our Independent Registered Public Accounting Firm" in the Proxy Statement.

PART IV.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

The financial statements and schedule listed in the Index to Financial Statements are filed as part of this Form 10-K.

(a)(2) Financial Statement Schedule.

Schedule II – Valuation and Qualifying Account

For the years ended December 31, 2007, 2006 and 2005:

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Deferred Tax Asset Valuation Allowance:				
2007	$9,323,000	$11,703,000		$21,026,000
2006	4,801,000	4,522,000		9,323,000
2005	1,668,000	3,133,000		4,801,000

(a)(3) Exhibits.

The exhibits required by this item are set forth on the Exhibit Index attached hereto.

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Fun City Popcorn, Inc., Lev Acquisition Corp. and Lev Pharmaceuticals, Inc., dated November 5, 2004 (incorporated by reference herein to Exhibit 2.1 to Form 8-K filed November 10, 2004).
2.2	Amendment No. 1 to Agreement and Plan of Merger by and among Fun City Popcorn, Inc., Lev Acquisition Corp. and Lev Pharmaceuticals, Inc., dated as of December 8, 2004 (incorporated by reference herein to Exhibit 2.2 to the Form 10-K/SB filed December 29, 2004).
3.1	Certificate of Incorporation (incorporated by reference herein to Exhibit A to the Information Statement on Schedule 14C filed January 26, 2005).
3.2	Bylaws (incorporated by reference herein to Exhibit B to the Information Statement on Schedule 14C filed January 26, 2005).
3.3	Amendment to Bylaws effective November 27, 2007 (filed as Exhibit 3.1 to Form 8-K filed December 3, 2007).
4.1§	Specimen of Common Stock Certificate.
4.2*	2004 Omnibus Incentive Compensation Plan (incorporated by reference herein to Exhibit 4.1 to Form 8-K filed January 4, 2005).
4.3	Form of Investor Warrant issued in connection with May 2005 Private Placement (incorporated by reference herein to Exhibit 4.1 to Form 8-K filed May 9, 2005).
4.4	Form of Agent Warrant issued in connection with May 2005 Private Placement (incorporated by reference herein to Exhibit 4.2 to Form 8-K filed May 9, 2005).
4.5	Warrant issued to Ashton Partners dated March 17, 2004 (incorporated by reference herein to Exhibit 4.4 to Registration Statement on Form SB-2/A filed on October 24, 2005).
4.6	Warrant issued to Lawler Scientific, LLC dated August 9, 2004 (incorporated by reference herein to Exhibit 4.5 to Registration Statement on Form SB-2/A filed on October 24, 2005).
4.7	Form of Warrant issued in connection with October 2006 Private Placement (incorporated by reference herein to Exhibit 4.1 to Form 8-K filed October 20, 2006).
4.8	Form of Warrant issued in connection with August 2007 Registered Offering (incorporated by reference herein to Exhibit 4.1 to Form 8-K filed August 14, 2007).
4.9	Form of Note issued to Lender dated November 2, 2007 (filed as Exhibit 4.1 to Form 10-QSB filed November 14, 2007).
4.10	Form of Warrant issued to Lender dated November 2, 2007 (filed as Exhibit 4.2 to Form 10-QSB filed November 14, 2007).
10.1*	Employment Agreement dated as of November 1, 2004 between Lev Pharmaceuticals, Inc. and Judson Cooper (incorporated by reference herein to Exhibit 10.1 to Form 8-K filed January 4, 2005).

10.2*	Employment Agreement dated as of November 1, 2004 between Lev Pharmaceuticals, Inc. and Joshua D. Schein (incorporated by reference herein to Exhibit 10.2 to Form 8-K filed January 4, 2005).
10.3	Distribution and Manufacturing Services Agreement between Lev Pharmaceuticals, Inc. and Sanquin Blood Supply Foundation dated as of January 16, 2004 (incorporated by reference herein to Exhibit 10.3 to Form 10-KSB filed March 31, 2005).#
10.3.1	First Amendment to the Distribution and Manufacturing Services Agreement between Lev Development Corp. and Sanquin Blood Supply Foundation dated as of January 30, 2006 (incorporated by reference herein to Exhibit 10.3.1 to Form 10-KSB filed March 31, 2006).
10.3.2	Amendment No. 2 to Distribution and Manufacturing Services Agreement between Lev Development Corp. and Sanquin Blood Supply Foundation dated as of January 31, 2006 (incorporated by reference herein to Exhibit 10.3.2 to Form 10-KSB filed March 31, 2006).#
10.4	Exclusive License Agreement between Lev Pharmaceuticals, Inc. and Sanquin Blood Supply Foundation dated as of January 27, 2004 (incorporated by reference herein to Exhibit 10.4 to Form 10-KSB filed March 31, 2005).#
10.5	Registration Rights Agreement dated as of March 19, 2004 (incorporated by reference herein to Exhibit 10.5 to Registration Statement on Form SB-2/A filed on October 24, 2005).
10.5.1	Form of Amendment No. 1 to 2004 Registration Rights Agreement dated as of July 21, 2005 (incorporated by reference herein to Exhibit 10.5.1 to Registration Statement on Form SB-2/A filed on October 24, 2005).
10.6	Form of Investor Registration Rights Agreement dated as of May 3, 2005 (incorporated by reference herein to Exhibit 10.1 to Form 8-K filed May 9, 2005).
10.6.1	Form of Amendment No. 1 to Registration Rights Agreement dated as of July 18, 2005 (incorporated by reference herein to Exhibit 10.6.1 to Registration Statement on Form SB-2/A filed on October 24, 2005).
10.7	Form of Placement Agent Registration Rights Agreement dated as of May 3, 2005 (incorporated by reference herein to Exhibit 10.2 to Form 8-K filed May 9, 2005).
10.7.1	Form of Amendment No. 1 to Placement Agent Registration Rights Agreement dated as of June 14, 2006 (incorporated by reference herein to Exhibit 10.7.1 to Post-Effective Amendment No. 1 to Registration Statement on Form SB-2 filed on June 16, 2006).
10.8	Investor Rights Agreement dated as of March 19, 2004 (incorporated by reference herein to Exhibit 10.8 to Registration Statement on Form SB-2/A filed on October 24, 2005).
10.9*	Employment Agreement dated as of June 7, 2006 between Lev Pharmaceuticals, Inc. and Douglas Beck (incorporated by reference herein to Exhibit 10.1 to Form 8-K filed June 12, 2006).
10.10*	Employment Agreement dated as of June 7, 2006 between Lev Pharmaceuticals, Inc. and Jason Bablak (incorporated by reference herein to Exhibit 10.2 to Form 8-K filed June 12, 2006).
10.11*	Employment Agreement dated as of August 2, 2006 between Lev Pharmaceuticals, Inc. and Joseph Truitt (incorporated by reference herein to Exhibit 10.2 to Form 8-K filed August 3, 2006).
10.12	Form of Securities Purchase Agreement dated as of October 16, 2006 (incorporated by reference herein to Exhibit 10.1 to Form 8-K filed on October 20, 2006).
10.13	Form of Registration Rights Agreement dated as of October 16, 2006 (incorporated by reference herein to Exhibit 10.2 to Form 8-K filed on October 20, 2006).
10.14	Form of Lease Agreement dated as of December 20, 2006 between Lev Pharmaceuticals, Inc. and DOLP 675 Properties II, LLC (incorporated by reference herein to Exhibit 10.1 to Form 8-K filed on December 22, 2006).
10.15*	Employment Agreement dated as of January 17, 2007 between Lev Pharmaceuticals, Inc. and Judson Cooper.
10.16*	Employment Agreement dated as of January 17, 2007 between Lev Pharmaceuticals, Inc. and Joshua D. Schein.
10.17*	Offer Letter dated March 16, 2007 between Lev Pharmaceuticals, Inc. and Dov Elefant
10.18#	Plasma Supply Agreement dated April 12, 2007 (filed as Exhibit 10.4 to Form 10-QSB/A filed October 27, 2007).
10.19#	Agreement for the Purchase and Sale of Blood Plasma dated July 12, 2007 (filed as Exhibit 10.1 to Form 8-K filed July 25, 2007).
10.20	Placement Agent Agreement, dated August 13, 2007, by and among the Company, Jefferies & Company, Inc., CIBC World Markets Corp. and Morgan Joseph & Co., Inc. (filed as Exhibit 10.1 to Form 8-K filed August 14, 2007).
10.21	Form of Subscription Agreement between the Company and each of the purchasers (filed as Exhibit 10.2 to Form 8-K filed August 14, 2007).
10.22#	Amendment to Distribution and Manufacturing Services Agreement with Sanquin Blood Supply Foundation, dated as of September 24, 2007 (filed as Exhibit 10.2 to Form 10-QSB filed November 14, 2007).
10.23	Term Loan Agreement dated as of November 2, 2007, by and among the Company, the Lender and Mast Capital Management, LLC (filed as Exhibit 10.3 to Form 10-QSB filed November 14, 2007).
10.24	Pledge and Security Agreement dated as of November 2, 2007, by and between the Company and Mast Capital Management, LLC (filed as Exhibit 10.4 to Form 10-QSB filed November 14, 2007).
10.25	Registration Rights Agreement dated as of November 2, 2007, by and among the Company and the Lender (filed as Exhibit 10.5 to Form 10-QSB filed November 14, 2007).

10.26*	Second Amended and Restated Employment Agreement between the Registrant and Judson Cooper (filed as Exhibit 10.1 to Form 8-K filed on December 21, 2007).
10.27*	Second Amended and Restated Employment Agreement between the Registrant and Joshua Schein (filed as Exhibit 10.2 to Form 8-K filed on December 21, 2007).
10.28*§	Form of Restricted Stock Award Agreement entered into with Messrs. Cooper and Schein.
14.1	Code of Ethics (incorporated by reference herein to Exhibit 14.1 to Form 10-KSB filed March 31, 2005).
21.1	Subsidiary of the Registrant (incorporated by reference herein to Exhibit 21.1 to Form 10-KSB filed March 31, 2005).
23.1§	Consent of Independent Registered Public Accounting Firm
31.1§	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2§	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1§	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2§	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement required.

§ Filed herewith.

Confidential treatment has been granted with respect to portions of this document pursuant to Rule 24b-2 of the Securities Exchange Act. The redacted portions of this document were filed separately with the Securities and Exchange Commission.

SIGNATURES

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

LEV PHARMACEUTICALS, INC.

March 14, 2008

By: /s/ Joshua D. Schein
Joshua D. Schein
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Joshua D. Schein, Ph. D. and Judson A. Cooper, his or her true and lawful attorneys-in-fact each acting alone, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead in any and all capacities to sign any or all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitutes, each acting alone, may lawfully do or cause to be done by virtue hereof.

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

NAME	TITLE	DATE
/s/ Joshua D. Schein Joshua D. Schein	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2008
/s/ Judson Cooper Judson Cooper	Chairman of the Board, Executive Vice President and Secretary	March 14, 2008
/s/ Douglas J. Beck Douglas J. Beck	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2008
/s/ Scott Eagle Scott Eagle	Director	March 14, 2008
/s/ Eric I. Richman Eric I. Richman	Director	March 14, 2008
/s/ Thomas Lanier Thomas Lanier	Director	March 14, 2008
/s/ Henry M. Dachowitz Henry M. Dachowitz	Director	March 14, 2008
/s/ Dov Elefant Dov Elefant	Corporate Controller	March 14, 2008

CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of
Lev Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Lev Pharmaceuticals, Inc. and subsidiary (the "Company") (a development stage enterprise) as of December 31, 2007 and 2006, the related consolidated statements of operations and cash flows for the periods from July 21, 2003 (inception) to December 31, 2007 and for each of the years in the three-year period ended December 31, 2007 and the consolidated statements of changes in stockholders' equity for each of the years in the three-year period ended December 31, 2007 and for the period from July 21, 2003 (inception) to December 31, 2004. 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Lev Pharmaceuticals, Inc. and subsidiary as of December 31, 2007, and 2006, and the consolidated results of their operations and their consolidated cash flows for the periods from July 21, 2003 (inception) to December 31, 2007 and for each of the years in the three-year period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the consolidated financial statements, the Company has incurred recurring losses from operations, has limited capital resources, and negative cash flows from operations which raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Lev Pharmaceuticals, Inc. and subsidiary's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2008 expressed an unqualified opinion thereon. As discussed in Note B to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation effective January 1, 2006.

/s/ Eisner LLP

New York, New York
March 13, 2008

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of
Lev Pharmaceuticals, Inc.

We have audited Lev Pharmaceuticals, Inc. and subsidiary (the "Company") internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control -Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Lev Pharmaceuticals Inc. and subsidiary, maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by COSO.

We have also audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Lev Pharmaceuticals., Inc. and subsidiary as of December 31, 2007 and 2006 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years in the three-year period ended December 31, 2007 and for the period from July 21, 2003 (inception) to December 31, 2007, and our report dated March 13, 2008, expressed an unqualified opinion which included an explanatory paragraph as to the Company's ability to continue as a going concern on those consolidated financial statements.

/s/ Eisner LLP

New York, New York
March 13, 2008

LEV PHARMACEUTICALS, INC. AND SUBSIDIARY
(a development stage enterprise)

Consolidated Balance Sheets	December 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,910,084	$ 7,887,635
Investments - held to maturity		9,999,845
Inventory	10,645,129	
Prepaid expenses	2,809,253	378,786
Other assets	5,695	82,030
Total current assets	35,370,161	18,348,296
Fixed assets, net of accumulated depreciation	272,401	131,094
Loan receivable	3,414,755	
Debt issuance costs	197,873	
Other assets	93,335	93,335
Total assets	$ 39,348,525	$ 18,572,725
LIABILITIES		
Current liabilities:		
Accounts payable	$ 1,997,263	$ 1,662,651
Accrued expenses	1,684,045	1,494,548
Total current liabilities	3,681,308	3,157,199
Loan payable, net of debt discount	4,381,092	1,803,554
Term loan payable, net of debt discount	9,185,454	
Deferred lease liability	16,423	
Total liabilities	17,264,277	4,960,753
Commitments and contingencies (See Note J)		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.01 par value, 20,000,000 authorized, no shares issued and outstanding		
Common stock - $0.01 par value, 200,000,000 shares authorized, 141,750,203 and 114,010,237 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively	1,417,502	1,140,102
Additional paid-in capital	71,936,511	35,660,209
Deficit accumulated during the development stage	(51,269,765)	(23,188,339)
Total stockholders' equity	22,084,248	13,611,972
Total liabilities and stockholders' equity	$ 39,348,525	$ 18,572,725

The accompanying notes are an integral part of the consolidated financial statements

LEV PHARMACEUTICALS, INC. AND SUBSIDIARY
(a development stage enterprise)

Consolidated Statements of Operations

	Years Ended			Period From July 21,2003 (Inception) to December 31,
	2007	2006	2005	2007
Costs and expenses:				
Research and development	$ 15,379,305	$ 7,167,459	$ 2,368,834	$ 26,049,531
Merger costs				283,732
General and administrative	13,110,974	4,835,444	4,110,005	25,432,055
Loss before other income	(28,490,279)	(12,002,903)	(6,478,839)	(51,765,318)
Other income:				
Interest income	912,962	281,852	181,895	1,427,621
Interest expense	(494,643)	(46,438)	(11,412)	(552,547)
Foreign exchange loss	(9,466)			(9,466)
Net loss	$ (28,081,426)	$ (11,767,489)	$ (6,308,356)	$ (50,899,710)
Net loss per share- basic and diluted	$ (0.23)	$ (0.13)	$ (0.08)	
Weighted average shares- basic and diluted	122,955,013	88,235,294	79,624,173	

The accompanying notes are an integral part of the consolidated financial statements

LEV PHARMACEUTICALS, INC. AND SUBSIDIARY
(a development stage enterprise)

Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2007, 2006 and 2005 and the Period From July 21, 2003 (Inception) to December 31, 2004

	Preferred Stock		Common Stock		Additional Paid-in	Subscription	Deficit Accumulated During the Development	
	Shares	Amount	Shares	Amount	Capital	Receivable	Stage	Total
Issuance of founders' shares ($0.01 per share) issued July 22, 2003			37,018,531	$370,185		$(130)	$(370,055)	$ 0
Sale of shares in December 2003 at $0.26 per share			1,141,960	11,420	$288,580			300,000
Proceeds from subscription receivable in December 2003						130		130
Net loss for the period from July 21, 2003 (inception) to December 31, 2003							(120,225)	(120,225)
Balance – December 31, 2003			38,160,491	381,605	288,580	0	(490,280)	179,905
Sale of common stock in February 2004 at $0.26 per share			3,425,879	34,259	865,741			900,000
Sale of common stock in February and March 2004 at $0.30 per share, net of issuance costs of $51,465			23,913,848	239,138	6,829,357			7,068,495
Issuance of warrants to purchase 7,327,576 shares of common stock to consultants at fair value, in March 2004					1,985,562			1,985,562
Issuance of warrants to purchase 111,341 shares of common stock to consultant at fair value, in August 2004					19,968			19,968
Cashless exercise of warrants in August 2004			6,297,571	62,976	(62,976)			0
Shares deemed issued in connection with Fun City Popcorn, Inc. merger on December 29, 2004			4,505,530	45,055	(109,518)			(64,463)
Issuance of Series A preferred stock and automatic conversion into common shares in connection with the merger of Fun City Popcorn, Inc. on December 29, 2004 (Note A)								
Modification of options and warrants in connection with merger treated as compensation expense					75,201			75,201
Net loss for the year ended December 31, 2004							(4,622,214)	(4,622,214)
Balance – December 31, 2004			76,303,319	763,033	9,891,915	0	(5,112,494)	5,542,454
Issuance of common stock and warrants in May 2005, at $1.00 per share, net of issuance cost of $679, 677			5,044,774	50,448	4,314,649			4,365,097
Repricing of warrant (Note I) in May 2005					27,819			27,819
Cashless exercise of warrant in September 2005			179,451	1,794	(1,794)			0
Issuance of warrants for services to purchase 50,000 shares of common stock at fair value in October 2005					11,329			11,329
Repricing of vested options to executive officers in December 2005					1,427,450			1,427,450
Net loss for the year ended December 31, 2005							(6,308,356)	(6,308,356)
Balance – December 31, 2005			81,527,544	815,275	15,671,368	0	(11,420,850)	5,065,793
Issuance of warrants to purchase 275,000 shares of common stock at fair value in January and June 2006 for services rendered					58,403			58,403
Issuance of common stock in May 2006 at $0.45 per share for services rendered			175,000	1,750	77,000			78,750
Stock based compensation					457,351			457,351
Issuance of common stock and warrants in October 2006, net of issuance costs: $1,415,255			32,307,693	323,077	19,261,668			19,584,745
Value of 125,000 vested warrants at fair value in December 2006 for services rendered					134,419			134,419
Net loss for the year ended December 31, 2006							(11,767,489)	(11,767,489)
Balance – December 31, 2006			114,010,237	1,140,102	35,660,209	0	(23,188,339)	13,611,972
Exercise of warrants			406,633	4,067	544,888			548,955
Stock based compensation					2,316,536			2,316,536
Issuance of common stock and warrants in August 2007 at $1.50 per share, net of issuance costs of $2,594,451			23,333,333	233,333	32,172,216			32,405,549
Value of warrants with the issuance of a term loan					1,098,019			1,098,019
Issuance of unvested restricted stock in December 2007			4,000,000	40,000	(40,000)			0
Compensation expense relating to restricted stock grant					184,643			184,643
Net loss for the year ended December 31, 2007							(28,081,426)	(28,081,426)
Balance – December 31, 2007			141,750,203	$1,417,502	$71,936,511	$0	$(51,269,765)	$22,084,248

The accompanying notes are an integral part of the consolidated financial statements

LEV PHARMACEUTICALS, INC. AND SUBSIDIARY
(a development stage enterprise)

Consolidated Statements of Cash Flows

	Years Ended December 31,			July 21, 2003 (Inception) to December 31,
Cash flows from operating activities:	2007	2006	2005	2007
Net loss	$ (28,081,426)	$ (11,767,489)	$ (6,308,356)	$ (50,899,710)
Adjustments to reconcile net loss to net cash used in operating activities:				
Compensation to consultants from issuance of warrants and common stock		192,822	10,825	2,209,177
Repricing of options and warrants			1,455,269	1,455,269
Option and warrants modification resulting from merger				75,201
Stock issued for services		78,750		78,750
Depreciation expense	59,098	19,542	10,474	89,400
Amortization of debt discount, loan payable	199,088	46,398	9,220	254,706
Amortization of debt discount and deferred financing costs, term loan payable	72,641			72,641
Accrued interest on term loan	222,471			222,471
Foreign exchange loss	9,466			9,466
Stock compensation to employees	2,316,536	457,351		2,773,887
Stock compensation for unvested restricted stock	184,643			184,643
Accretion of investment income		(12,610)		(12,610)
Gain on sale of investments	(155)			(155)
Supplier purchase funding	1,764,343	1,286,318	322,000	3,372,671
Foreign exchange loss/ (gain) on research and development	614,107	154,761	(15,143)	753,715
Deferred lease liability	16,423	(2,519)	(2,338)	16,423
Changes in:				
Inventory	(10,645,129)			(10,645,129)
Prepaid expenses and other assets	(2,354,131)	(200,424)	(31,028)	(2,907,778)
Accounts payable	334,612	1,005,421	657,230	1,997,263
Accrued expenses	189,497	1,142,512	108,411	1,684,045
Income taxes liability			(82,916)	(64,463)
Net cash used in operating activities	(35,097,916)	(7,599,167)	(3,866,352)	(49,280,117)
Cash flows from investing activities:				
Purchase of fixed assets	(200,405)	(80,714)	(73,246)	(361,801)
Loan receivable	(3,424,221)			(3,424,221)
Proceeds from the sale of investments	10,000,000			12,500,000
Purchase of investments		(7,499,845)	(2,487,390)	(12,487,235)
Net cash provided by (used in) investing activities	6,375,374	(7,580,559)	(2,560,636)	(3,773,257)
Cash flows from financing activities:				
Proceeds from stock subscription receivable				130
Proceeds from notes payable to stockholder				18,000
Proceeds from term loan payable	10,000,000			10,000,000
Payment of debt issuance costs	(209,513)			(209,513)
Repayment of notes payable to stockholder				(18,000)
Net proceeds from sale of common stock and warrants	32,405,549	19,584,745	4,365,097	64,623,886
Proceeds from exercise of warrants	548,955			548,955
Net cash provided by financing activities	42,744,991	19,584,745	4,365,097	74,963,458
Net increase (decrease) in cash and cash equivalents	14,022,449	4,405,019	(2,061,891)	21,910,084
Cash and cash equivalents - beginning of period	7,887,635	3,482,616	5,544,507	
Cash and cash equivalents – end of period	$ 21,910,084	$ 7,887,635	$ 3,482,616	$ 21,910,084

Supplemental non-cash financing activities:

During the year ended December 31, 2007, in connection with a term loan, the Company issued warrants to purchase 900,000 shares of common stock at an exercise price of $1.66 that vested immediately and expire in three years. The fair value of these warrants was $1,098,019 using the Black Scholes option pricing model.

The accompanying notes are an integral part of the consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE A - ORGANIZATION AND BUSINESS

Fun City Popcorn, Inc. ("FCP"), a non-operating public company, was incorporated on September 18, 1985 in the State of Nevada.

On November 5, 2004, FCP entered into an agreement and plan of merger (the "Agreement") with Lev Development Corp., formerly known as Lev Pharmaceuticals, Inc. ("Lev"), which was incorporated on July 21, 2003 in the State of Delaware. Lev is a development stage company which is engaged in developing and commercializing therapeutic products for the treatment of inflammatory diseases. On December 29, 2004, the merger closed and pursuant to the Agreement, FCP acquired 100% of the outstanding capital stock of Lev through its subsidiary Lev Acquisition Corp. ("LAC"). In connection with the merger, FCP subsequently changed its name to Lev Pharmaceuticals, Inc. and increased its authorized common stock to 200,000,000 shares and its authorized preferred stock to 20,000,000 shares. Under the terms of the Agreement, the stockholders of Lev exchanged all of their issued and outstanding shares of common stock for 5,029,795 shares of FCP common stock, and 4,789,433 shares of FCP Series A voting convertible preferred stock (the "Exchange"). Each Series A voting convertible preferred share was converted automatically into 13.940668 shares of FCP common stock (an aggregate of 66,767,994 common shares). The 71,797,789 shares of common stock represented approximately 94.10% of the ownership interests in FCP following the merger. In addition, 4,505,530 shares of common stock of FCP were deemed issued and outstanding in connection with the Exchange. In addition, all of the outstanding Lev options and warrants immediately prior to the merger were exchanged for 2,854,900 FCP options and 301,668 FCP warrants. The Exchange, which resulted in the stockholders of Lev having control of FCP, represents a recapitalization of FCP, or a "reverse merger" rather than a business combination. In connection therewith, FCP's historical capital accounts were retroactively adjusted to reflect the equivalent number of shares issued by FCP in the Exchange while Lev's historical accumulated deficit was carried forward. The statement of operations reflects the activities of Lev from the commencement of its operations on July 21, 2003. In connection with the Agreement, Lev agreed to acquire FCP for $350,000. In December 2004, Lev paid certain FCP stockholders $283,731 which represents the acquisition price of $350,000 less the assumption of a tax liability of $66,269. In connection with the Exchange, the exercise price of the outstanding warrants and options remained the same. The Company recorded a charge of approximately $75,000 for the change in value of the Company's outstanding options and warrants as of December 29, 2004 as a result of the increase in the number of common shares into which these equity instruments are exercisable based on the exchange ratio used in the merger, since the aggregate intrinsic value of the warrants and options after the Exchange is greater than before. The Black-Scholes option-pricing model was used to calculate the value of certain options and warrants and the related charge based upon the following weighted average assumptions to determine fair value: risk-free interest rate of 3.58%; expected life of 5 years; dividend yield of 0%; and expected volatility of 70%.

NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

[1] Basis of presentation:

The consolidated financial statements include the accounts of Lev Pharmaceuticals, Inc. and its wholly-owned subsidiary, Lev Development Corp. All significant intercompany transactions and balances have been eliminated in consolidation. There has been no revenue generated from sales, license fees or royalties. There have been sales of residual plasma during 2007, however, the Company does not deem this to be its principal operations. The proceeds have been recorded as a reduction to research and development expense and inventory. The Company's financial statements are presented as statements of a development stage enterprise.

The Company has prepared its financial statements under the assumption that it is a going concern. As a development stage enterprise, the Company's primary efforts are devoted to conducting research and development for the treatment of inflammatory diseases. As the Company has limited capital resources and has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future, the Company raised capital from the sales of its securities to sustain operations. As of December 31, 2007, the Company had approximately $21.9 million in cash and cash equivalents. In August 2007, the Company raised net proceeds of approximately $32.4 million in a registered direct sale of its securities (see Note I) and in November 2007, we entered into a secured loan facility for a term loan of up to $20.0 million and received an initial loan of $10.0 million on the closing date (see Note H). Pursuant to this facility, we have the option to request additional borrowings of a maximum of $10.0 million for the twelve months following the closing date subject to the terms of the loan. We have cash commitments of $39.6 million through December 31, 2008. We expect that our cash used in operations will increase significantly over the next several years and we may be required to raise additional capital to complete the development and commercialization of our current product candidates. Management believes that cash and cash equivalents on hand as of December 31, 2007 should be sufficient to fund operations for the next six months. These factors

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

[1] Basis of presentation (continued):

raise substantial doubt about the ability of the Company to continue as a going concern. The Company does not have any commercial products available for sale and has not generated significant revenues and there is no assurance that if approval of their products is received that the Company will be able to generate cash flow to fund operations. We may pursue equity or debt financing alternatives or other financing in order to raise additional funds; however, we do not have any commitments or definitive or binding arrangements for such funds. There can be no assurance that such funds, if available at all, can be obtained on terms reasonable to the Company. If we are unsuccessful in raising additional capital we will need to reduce costs and operations substantially. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

[2] Cash and cash equivalents:

The Company considers all highly liquid investments which have maturities of three months or less when purchased, to be cash equivalents.

[3] Patents:

The Company has applied or is applying for a number of patents to protect proprietary inventions. All costs associated with patents are expensed as incurred.

[4] Research and development costs:

The Company expenses all research and development costs as incurred including equipment for which there is no alternative future use. Such expenses include licensing fees and costs associated with planning and conducting clinical trials.

[5] Investments:

Securities that the Company has the positive intent and ability to hold to maturity are classified as held-to-maturity and are carried at amortized cost on the balance sheets.

[6] Inventory:

Inventory is stated at the lower of cost or market using the first-in-first-out method. As of December 31, 2007, inventory consisted of $9,680,317 of raw materials and $964,812 of work-in-process.

[7] Sale of residual plasma:

Sales of residual plasma resulting from the manufacturing process of our product is treated as a cost-recovery at the time of the delivery as a reduction to research and development expense and inventory. The Company does not deem these sales to be its principal operation.

[8] Concentration of credit risk:

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents. As of December 31, 2007, the Company had approximately $21,710,084 over the FDIC limit.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

[9] Fixed Assets:

Fixed assets are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life, which is three or five years.

[10] Income taxes:

The Company accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS No. 109"). SFAS No. 109 requires that the Company recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records an estimated valuation allowance on its deferred income tax assets if it is not more than likely that these deferred income tax assets will be realized.

The Company adopted the provisions of Financial Standards Accounting Board Interpretation No. 48 Accounting for Uncertainty in Income Taxes ("FIN 48") an interpretation of FASB Statement No. 109 ("SFAS 109") on January 1, 2007. As a result of the implementation of FIN 48, we did not recognize any adjustment in the liability for unrecognized income tax benefits. The tax years 2003-2006 remain open to examination by the major taxing jurisdictions to which we are subject. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

[11] Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include valuation of warrants issued in connection with the term loan, imputed interest rate on Sanquin loan and assumptions used in the fair value of stock based compensation.

[12] Debt issuance costs:

Costs incurred to obtain debt financing are recorded as debt issuance costs. The costs are amortized using the effective interest rate method over the life of the debt.

[13] Stock-based compensation:

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standard No. 123(R), "Share Based Payment" ("SFAS No. 123(R)"), which requires all stock-based payments, including grants of stock options, to be recognized in the Statement of Operations as compensation expense, based on their fair values on the grant date. Under SFAS No.123(R), the estimated fair value of options granted under the Company's Employee 2004 Omnibus Incentive Compensation Plan ("Plan") as well as options granted outside the plan are recognized as compensation expense over the option-vesting period. The Company adopted SFAS No. 123(R), using the modified-prospective-transition method, in which compensation expense is recognized beginning with the effective date of the adoption for all stock-based payments (i) granted after the effective date of adoption and (ii) granted prior to the effective date of adoption but not vested on the date of adoption, based upon the grant date fair value estimated in accordance with the original provisions of SFAS No. 123. During the years ended December 31, 2007 and 2006, the Company recorded $2,316,536 and $457,351, respectively, of stock-based employee compensation expense.

Prior to January 1, 2006, the Company applied APB Opinion No. 25, Accounting for Stock Issued to Employees, in accounting for its stock option plans. Under the provisions of APB 25, no compensation expense was recognized when stock options were granted with exercise prices equal to or greater than market value on the date of grant, provided that pro forma net loss and net loss per share disclosures were made as required by the original provisions of SFAS No. 123.

[13] Stock-based compensation (continued):

The following table illustrates the effect on net loss and loss per share if the fair value method had been applied under SFAS No. 123 to the prior period.

	Year Ended December 31, 2005
Net loss applicable to common shareholders, as reported	$ (6,308,356)
Add: Total stock-based employee compensation expense determined under fair value method	(470,051)
Less: Stock based employee compensation related to Repricing including in net loss as recorded	$ 1,427,450
Pro forma net loss	$ (5,350,957)
Basic and diluted loss per share	
As reported	$ (0.08)
Pro forma	$ (0.07)

The following table illustrates the breakdown of total stock compensation expense by function for the year ended December 31, 2007 and 2006:

Stock option expense by function:

	Years Ended December 31, 2007	2006
Research and development expense before stock option expense	$ 15,206,078	$ 6,991,341
Stock option expense	173,227	176,118
Research and development expense	$ 15,379,305	$ 7,167,459
General and administrative expense before stock option expense	$ 10,967,665	$ 4,554,211
Stock option expense	2,143,309	281,233
General and administrative expense	$ 13,110,974	$ 4,835,444

Under the modified prospective method of transition under SFAS No. 123(R), the Company is not required to restate its prior period financial statements to reflect expensing of stock-based compensation under SFAS No. 123(R). Therefore, the results for the years ended December 31, 2007 and 2006 are not directly comparable to the same period in the prior year.

Prior to the adoption of SFAS No. 123(R), the Company presented cash flows resulting from the tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the Consolidated Statement of Cash Flows. SFAS No. 123(R) requires cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. The Company did not realize any tax benefits from stock options during the years ended December 31, 2007 and 2006.

For purposes of the disclosure in the foregoing table and for purposes of determining estimated fair value under SFAS No.123(R), the Company has computed the estimated fair values of all share-based compensation using the Black-Scholes option -pricing model and has applied the assumptions set forth in the following table. The Company calculated expected volatility based upon comparable companies in the industry for 2005 and historical volatility of the Company's common stock in 2006 and 2007. The weighted-average fair value of options granted in 2005, 2006 and 2007 under the Plan was approximately $0.73, $0.64 and $1.45, respectively. The expected term was calculated using the simplified method as prescribed under Staff Accounting Bulletin No. 107 and as amended by No. 110 as issued by the Securities and Exchange Commission. The following table illustrates the assumptions used in the Company's Black-Scholes option pricing model to determine the stock option expense for options granted under the Plan for the years ended December 31, 2007, 2006 and 2005.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

[13] Stock-based compensation (continued):

	Risk Free Interest Rate	Dividend Yield	Volatility Factor	Estimated Life (Years)
For the year ended December 31, 2007	4.48% - 4.80%	0%	124%-131%	4.97
For the year ended December 31, 2006	4.77% - 4.99%	0%	132%-157%	4.50-6.25
For the year ended December 31, 2005	3.58% - 4.39%	0%	70.0%	5

During 2007 the Company granted options outside the Plan. The weighted-average fair value of options granted in 2007 outside the Plan was approximately $1.38. The following table illustrates the assumptions used in the Company's Black-Scholes option pricing model to determine the stock option expense for options granted outside the Plan for the year ended December 31, 2007.

	Risk Free Interest Rate	Dividend Yield	Volatility Factor	Estimated Life (Years)
For the year ended December 31, 2007	3.90% - 4.15%	0%	105%-106%	4.32

The Black-Scholes option-pricing model requires the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models may not provide a reliable single measure of the fair value of its employee stock options. In addition, management will continue to assess the assumptions and methodologies used to calculate estimated fair value of share-based compensation. Circumstances may change and additional data may become available over time, which can result in changes to these assumptions and methodologies, which could materially impact the Company's fair value determination.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

[13] Stock-based compensation (continued):

Plan options

A summary of option activity under the Plan as of December 31, 2007, 2006 and 2005 and the changes during the years then ended is presented below.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2004	3,529,900	$ 0.84		
Granted	2,954,900	0.33		
Cancelled	(2,854,900)	(0.85)		
Outstanding, December 31, 2005	3,629,900	$ 0.42		
Granted	1,965,000	0.66		
Outstanding, December 31, 2006	5,594,900	$ 0.50		
Granted	4,390,000	1.63		
Outstanding, December 31, 2007	9,984,900	$ 1.00	7.79	$9,216,438
Vested and expected to vest, December 31, 2007	9,984,900	1.00	7.79	$9,216,438
Exercisable shares as of December 31, 2007	4,565,733	$ 0.46	7.11	$6,657,621

Summary Details for Plan:

There were no options canceled or exercised during the years ended December 31, 2007, 2006 and 2005. The grant date fair value and weighted average grant date fair value per share of options granted during the years ended December 31, 2007, 2006 and 2005 was $6,384,970 or $1.45 per share, $1,248,491or $0.60 per share and $73,202 or $0.73 per share, respectively, using the Black Scholes option pricing model. For the year ended December 31, 2006 the Company recorded $127,863 as research and development expense for the value of performance-based options to purchase 120,000 shares of common stock since the performance measure was met during the year.

As of December 31, 2007, there was $5,319,766 of total unrecognized compensation expense related to unvested share-based compensation arrangements granted under the Plan. The remaining expense is expected to be recognized over a weighted-average period of 30 months.

Out of Plan options

A summary of option activity outside the Plan as of December 31, 2007 is presented below.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2006	0			
Granted	2,165,273	$ 1.83		
Outstanding, December 31, 2007	2,165,273	1.83	6.87	$ 203,916
Vested and expected to vest, December 31, 2007	2,165,273	1.83	6.87	$ 203,916
Exercisable shares as of December 31, 2007	120,000	$ 1.82	6.87	$ 12,200

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

[13] Stock-based compensation (continued):

Summary Details for options outside the Plan:

There were no options canceled or exercised during the year ended December 31, 2007. The weighted average, grant date fair value of options granted during the year ended December 31, 2007 was $2,992,511 or $1.38 per share, using the Black Scholes option pricing model.

As of December 31, 2007, there was $2,659,450 of total unrecognized compensation expense related to unvested share-based compensation arrangements granted outside the Plan. The remaining expense is expected to be recognized over a weighted-average period of 34 months.

[14] New Accounting Pronouncements:

On September 15, 2006 the Financial Accounting Standards Board ("FASB") issued Statement No. 157, Fair Value Measurements. The Statement provides guidance for using fair value to measure assets and liabilities. This Statement references fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The Statement applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The Statement does not expand the use of fair value in any new circumstances. It is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The adoption of SFAS No. 157 is not expected to have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115" (SFAS 159), which permits entities to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective as of the beginning of fiscal years after November 15, 2007. We are currently evaluating the impact that SFAS 159 will have on our consolidated financial position, results of operations, and cash flows as of its adoption in 2008.

In December 2007, the SEC issued SAB 110, codified as part of SAB Topic 14.D.2, "Share-Based Payment: Certain Assumptions Used in Valuation Methods - Expected Term." SAB 110 permits companies, under certain circumstances, to continue to use the simplified method when calculating the expected term of "plain vanilla" share options. Originally, the simplified method was due to expire on December 31, 2007. A company may use the simplified method if it concludes that it is not reasonable to base its estimate of expected term on its experience with exercising historical share options. The effective date for SAB 110 is January 1, 2008. Management is in the process of assessing whether the Company will continue to use the simplified method for stock option grants after January 1, 2008.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) ("SFAS 141R"), "Business Combinations" and SFAS No. 160 ("SFAS 160"), "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulleting No. 51." SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interest and classified as a component of equity. SFAS 141R and SFAS 160 are effective beginning the first fiscal quarter of 2009. Early adoption is not permitted. The Company does not expect the adoption of either SFAS 141R or SFAS 160 will have a material impact on its statements of financial position, results of operations and cash flows. The guidance in these pronouncements will be effective for any acquisitions closed by the Company in the fiscal year 2009.

[15] Net loss per share:

Basic net loss per share is computed on the basis of net loss for the period divided by the weighted average number of shares of common stock outstanding during the period, excluding unvested restricted stock. There were potentially dilutive common shares of 36,539,344, 20,824,037 and 6,994,672 as of December 31, 2007, 2006 and 2005, respectively, related to stock options,

[15] Net loss per share (continued):

warrants and unvested restricted stock for 2007, which were excluded from the diluted loss per share calculation since their effect would have been anti-dilutive.

[16] Fair Value of financial instruments:

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, short-term investments, accounts payable and accrued expenses are shown at cost which approximates fair value due to the short-term nature of these instruments. The fair value of the debt approximates the carrying value as the interest rates are generally variable based on market interest rates and reflect current market rates available to the Company.

NOTE C - INVESTMENTS

Investments with original maturities of 91 days to one year are considered short term investments and are carried at amortized cost. Investments as of December 31, 2006 consisted of $4,999,845 in an Adjustable Rate Preferred Security and a Certificate of Deposit for $5,000,000.

NOTE D – PREPAID EXPENSES

Prepaid expenses consist of the following:

	For the years ended December 31,	
	2007	2006
Advance for plasma purchases	$2,339,674	
Prepaid insurance	451,499	$289,089
Prepaid other	18,080	89,697
Total	$2,809,253	$378,786

NOTE E – FIXED ASSETS

Fixed assets consist of the following:

	For the years ended December 31,	
	2007	2006
Office equipment	$ 274,957	$ 149,750
Lab equipment	11,645	11,645
Other	75,198	
Total	361,800	161,395
Accumulated depreciation	(89,399)	(30,301)
Net	$ 272,401	$ 131,094

Depreciation expense for the years ended December 31, 2007, 2006 and 2005 was $59,098, $19,542 and $10,474, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE F – ACCRUED EXPENSES

Accrued expenses consist of the following:

	For the years ended December 31,	
	2007	2006
Research and development – sponsored research	$234,000	$234,000
Research and development – clinical	413,554	480,000
Research and development – consulting		94,000
Research and development – other		79,540
Research and development – payroll	24,604	28,756
General and administrative – professional fees	179,000	60,000
General and administrative – payroll	326,333	487,380
General and administrative – other	78,887	30,872
Sanquin facility upgrade	324,187	
Other	103,480	
Total	$1,684,045	$1,494,548

NOTE G – LOAN PAYABLE

The Company purchases its C1-INH product from the Sanquin Blood Supply Foundation ("Sanquin"). Under the agreement with Sanquin, Sanquin provides a loan to the Company for the value of C1-INH purchased for clinical trials. The loans are subject to a purchase money security interest. Upon regulatory approval, Sanquin will forgive each loan and release all security interests. If regulatory approval is not obtained, then each loan is payable on the earlier of January 16, 2014 or the termination of the agreement. The principal loan balances outstanding as of December 31, 2007 and 2006 was $4,381,092 net of debt discount of $1,872,846 and $1,803,554 net of debt discount of $959,140, respectively. This debt discount relates to interest imputed on the original loan balance as it is non-interest bearing and was recorded as a reduction to product costs that were included as research and development expense. We fulfilled the loan purchase commitment in August 2007 at which time the aggregate loan amount became fixed, subject to foreign exchange fluctuations. The loans are payable in Euros and any currency differences are recorded in our Consolidated Statement of Operations as a research and development expense. The Company has recorded interest expense using the effective interest rate method. Interest rates range from 4.31% to 7.66%. For the years ended December 31, 2007, 2006 and 2005, interest expense was $199,088, $46,438 and $9,220 respectively. The amount included in research and development expense for product cost for the years ended, December 31 2007, 2006 and 2005 was $1,764,343, $1,286,318 and $322,000, respectively. For the years ended December 31, 2007 and 2006, foreign exchange loss was $614,107 and $154,761, respectively. For the year ended December 31, 2005 the Company recorded a foreign exchange gain of $15,143.

NOTE H – TERM LOAN PAYABLE

On November 2, 2007, the Company and its wholly-owned subsidiary, Lev Development Corp. entered into a Term Loan Agreement dated as of November 2, 2007 (the "Loan Agreement") and a Pledge and Security Agreement of the same date (the "Security Agreement" and together with the Loan Agreement, the "Secured Financing Agreements"), among the Company, the Lender executing the Loan Agreement (the "Lender") and Mast Capital Management, LLC ("Mast"), as agent for the Lender.

Under the Loan Agreement, the Lender agreed to provide a term loan facility to the Company in an aggregate amount of up to $20,000,000. The loan is secured by a first priority lien on all of the Company's assets. Pursuant to the terms and conditions of the Secured Financing Agreements, at the initial closing the Company received an initial loan of $10,000,000. Subsequent term loan advances may be requested by the Company in amounts not less than $1,000,000 each during the twelve month period from the closing date. The Company's ability to request additional loans is subject to the Company maintaining (i) a borrowing base in excess of the outstanding aggregate loan amount and (ii) compliance with the covenants and conditions of the loan. The loan is for a term of 36 months and matures on November 1, 2010. Interest on the loan accrues at the rate of 13.5% per annum and has an effective interest rate of 26.6%. As of December 31, 2007, the principal balance of the loan outstanding was $10,000,000 with accrued interest owed of $222,471 net of debt discount of $1,037,017. Commencing November 1, 2008, the Company must pay minimum cash interest payments of 10.5% and an additional 3% accrues through the term of the loan.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE H – TERM LOAN PAYABLE (CONTINUED):

The Loan Agreement allows the Company to prepay the outstanding principal amount and all accrued but unpaid interest, subject to payment of a make-whole premium during the first year following the closing and a prepayment fee thereafter, until May 1, 2010. The Loan Agreement requires compliance with customary covenants and restrictions on the Company's ability to, among other things, dispose of certain assets, engage in certain transactions, incur indebtedness and pay dividends. In addition, the Loan Agreement requires compliance with financial covenants that commence December 31, 2008. The Loan Agreement also provides for customary events of default following which, the Lender may, at its option, accelerate the amounts outstanding under the Loan Agreement.

In connection with the Loan Agreement, the Company issued to the Lender warrants to purchase an aggregate of 900,000 shares of Company common stock (the "Warrants"). The Company valued the warrants at $1,098,019 using the Black Scholes option pricing model and is deemed a debt discount. The debt discount is netted against the term loan and amortized over the life of the loan and is charged to interest expense. The Warrants are for a term of three years and have an exercise price of $1.6576 per share, which is the volume weighted average price per share of the Company's common stock for the thirty trading days immediately preceding the closing. The Company also entered into a registration rights agreement with the Lender pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock which may be issued upon exercise of the Warrants upon the demand of the holders of a majority of the Warrants. If no registration statement is filed and declared effective by the Securities and Exchange Commission covering the resale of the shares of common stock which may be issued upon exercise of the Warrants, the lender may exercise the warrants for unregistered shares of common stock. In consideration for services provided on behalf of the Company in connection with the consummation of the transactions contemplated by the Secured Financing Agreements, the Company paid $100,000 which was a fee of 1% of the amounts borrowed under the Loan Agreement to Mr. Richard Stone, who is the beneficial owner of greater than 5% of the Company's outstanding common stock.

On February 11, 2008, the Lender, agent for the Lender and two affiliated individuals filed a Schedule 13G with the Securities and Exchange Commission reporting that as of January 30, 2008, such persons were the beneficial owner of greater than 5.0% of the Company's common stock. Accordingly, in the event that the Company elects to increase its borrowings under this loan arrangement, such transaction would be reviewed by the audit committee of the Company's board of directors in accordance with its procedures for reviewing related party transactions.

NOTE I – STOCKHOLDERS EQUITY

[1] Common stock:

The Company issued 37,018,531 shares of common stock at $0.01 par value to its founders (the "Founders' Shares") effective July 22, 2003 and recorded subscriptions receivable of $130. The Company increased its accumulated deficit by $370,055 in connection with the par value differential of the shares relating to FCP.

In December 2003, the Company received proceeds of $300,000 through the sale of 1,141,960 shares of common stock to a single investor at $0.26 per share and received the payment of the $130 subscription receivable.

Between February and March 2004, the Company received proceeds of approximately $7,968,000, net of issuance costs of approximately $51,000, from the sale of 3,425,879 shares of common stock at $0.26 per share and of 23,913,848 shares of common stock at $0.30 per share.

In February 2005, the Company increased its authorized common stock to 200,000,000 shares and its authorized preferred stock to 20,000,000 shares.

In May 2005, the Company completed a private placement of units and raised gross proceeds of $5,044,774 from the sale of 100.9 units. Each unit was sold at a price of $50,000 and consisted of 50,000 shares of common stock and a five-year warrant to purchase 25,000 shares of common stock at an exercise price of $1.35 per share. The Company's net proceeds were $4,365,097 after payment of fees and expenses, including the estimated costs of registering the shares of common stock for resale. The Company paid $454,030 to the placement agent and issued warrants to the placement agent to purchase 681,044 shares of common stock. These warrants are exercisable at $1.35 per share and expire in May 2010. The Company issued an aggregate of 5,044,774 shares of common stock and warrants to purchase 2,522,387 shares of common stock to investors in this private placement, not including the warrants issued to the placement agent. The Company entered into a registration rights agreement

[1] Common stock (continued):

in connection with a private placement that requires the Company to file a registration statement for the resale of shares of common stock and common stock issuable upon the exercise of warrants. The Company was required to use commercially reasonable efforts to have the registration statement declared effective by October 24, 2005. The Securities and Exchange Commission declared the registration statement effective on October 24, 2005. In addition, the Company is required to use its commercially reasonable efforts to maintain the effectiveness of the registration statement until the earlier date when all registrable securities (a) have been sold pursuant to the registration statement or an exemption from the registration requirements of the Securities Act, or (b) two years from the date of the effectiveness of the registration statement. If the Company fails to maintain the effectiveness of the registration statement pursuant to the registration rights agreement then the Company is required to make a cash payment of liquidated damages to the investors of 1% of the amount paid by the investors for each 30 day period, until such deficiency is cured.

The Company has accounted for the registration rights agreement as a separate freestanding instrument and treated the liquidated damages provision as a derivative liability subject to SFAS No. 133. The liability would be recorded once it is both probable of being incurred and the amount of the liability is estimable. The Company determined that as of December 31, 2007 it is not probable that any amounts will be paid under the registration rights agreement.

On May 4, 2006, the Company entered into a one-year consulting agreement for services from an investor relations firm. The Company issued 175,000 shares of common stock at a fair value of $78,750. An additional 175,000 shares were issuable in six months if the agreement was not cancelled. The Company cancelled this agreement on November 1, 2006. The monthly fee was $10,000.

On October 16 and October 20, 2006, the Company closed on a private placement for the sale of a combined aggregate of $21,000,000 million of its securities sold in units to certain institutional and other accredited investors. The units consist of 32,307,693 shares of the Company's common stock and warrants to purchase 9,692,308 shares of common stock, at a purchase price of $0.65 per share. The warrants are exercisable at any time until five years from the initial closing date at a price of $0.84 per share. The Company paid commissions of $1,279,593 and issued 1,698,538 and 198,519 warrants to registered broker-dealers that assisted in the financings (the "Agent Warrants"). The Agent Warrants were issued at $0.84 and $1.18 per share, respectively, and expire five years from the date of issuance. The Company paid $1,415,255 in offering expenses and the net proceeds were $19,584,745. A registration rights agreement was entered into in connection with the private placement that required the Company to file a registration statement for the resale of shares of common stock and common stock issuable upon the exercise of the warrants. The Company was required to use commercially reasonable efforts to have the registration statement declared effective within 120 days from the filing date, or 180 days from such date if the SEC undertakes a full review of the registration statement. In addition, the Company is required to maintain effectiveness for two years. If the Company failed to have the registration statement declared effective within the prescribed time period, then the Company would have been required to issue 630,000 warrants as liquidated damages to the investors.

The Company accounts for the registration rights agreement as a separate freestanding instrument and accounts for the liquidated damages provision as a derivative liability subject to SFAS 133. The liability would be recorded once it is both probable of being incurred and the amount of the liability is estimable. The Company determined that as of December 31, 2007 it is not probable that any amounts will be paid under the registration rights agreement.

On August 17, 2007, the Company closed on a registered direct sale to certain institutions of an aggregate of units consisting of 23,333,333 shares of its common stock and warrants to purchase up to an aggregate of 4,666,667 shares of its common stock for aggregate proceeds of $35.0 million. The warrants are exercisable at any time until five years from the closing date at a price of $1.86. The Company paid $2,594,451 in total offering expenses and the net proceeds was $32,405,549. These securities were sold pursuant to an effective registration statement.

On December 20, 2007, the Company granted 4,000,000 shares of restricted common stock to the Chief Executive Officer and Chairman with the following vesting schedule: 50% of the restricted stock shall vest and the restrictions thereon shall lapse upon receipt of FDA approval for Cinryze™ and thereafter 25% of the restricted stock shall vest and the restrictions thereon shall lapse on each of the first and second anniversaries of FDA approval. The Company has determined that it is probable as of December 31, 2007 that the restricted shares will start to vest in August 2008. The Company cannot provide any assurances as to when it may receive FDA approval and in the event that FDA approval is not obtained by such date, the Company will revise its estimates regarding these awards. Therefore, the Company recorded compensation expense of $184,643 for the period December 20, 2007 to December 31, 2007 based upon the value of the common stock. As of December 31, 2007, there was $7,335,357 of total unrecognized compensation expense related to the restricted stock.

[2] Warrants:

In February 2004, the Company entered into an engagement agreement (the "Engagement Agreement") with a placement agent (the "Placement Agent"), under which the Placement Agent was engaged to raise funds and assist the Company in an initial public offering. The Engagement Agreement also provided for the sale to the Placement Agent of a contingent warrant for $100,000 to purchase up to 35,686,243 shares of common stock. The Placement Agent raised approximately $550,000 for the Company in February 2004. In June 2004, the Company entered into an amended and restated engagement agreement (the "Amended Engagement Agreement") which replaced the Engagement Agreement. In connection with the Amended Engagement Agreement, the warrant to purchase 35,686,243 shares of common stock was cancelled and terminated, and the Placement Agent would receive a defined number of warrants, exercisable at $0.85 per share to purchase up to a maximum of 7,137,249 shares of the Company's common stock based on the amount of funds raised from investors introduced by the Placement Agent. In addition, the Placement Agent would receive a defined amount of cash compensation. The Company was responsible for all expenses in connection with the private placement. No funds were raised under the Amended Engagement Agreement, which expired on September 1, 2004 and no warrants were issued thereunder.

In March 2004, the Company granted fully vested warrants to two consultants, who had assisted the Company with developing its strategic business plan, obtaining its license for the C1-INH product and consulting on its corporate structure. The warrants are for the purchase of 7,327,576 shares of common stock at an exercise price of $0.10 per share, expiring in March 2014. The aggregate fair value of the warrants using the Black-Scholes option-pricing model totaled approximately $1,986,000. The weighted-average assumptions used to determine the fair values of the warrants are as follows: risk-free interest rate of 2.64%; expected warrant life of 5 years; dividend yield of 0% and expected volatility of 70%. On August 23, 2004, one of the consultants exercised warrants covering 7,137,249 shares of common stock in a net share settlement. The warrant exercise price of $250,000 was satisfied by reducing the number of shares exercised. The Company issued 6,297,571 shares of common stock. On September 12, 2005, one of the consultants exercised on a cashless basis warrants to purchase 190,327 shares of common stock and the Company issued 179,451 shares of stock. See Note K – Stock Options and Warrants. The warrant exercise price was satisfied by reducing the number of shares exercisable.

In August 2004, the Company granted to a consultant, who had assisted the Company with its development programs and clinical trial design, warrants to purchase 111,341 shares of common stock at an exercise price of $0.85 per share, expiring in August 2014. The aggregate fair value of the warrants on their issuance date, using the Black-Scholes option-pricing model, was approximately $20,000. The weighted-average assumptions used to determine the fair values of the warrants are as follows: risk-free interest rate of 3.38%; expected warrant life of 5 years; dividend yield of 0% and expected volatility of 70%.

In October 2005, the Company entered an agreement for public and investor relation services which was subsequently cancelled during 2006. The consultant was compensated partly in cash and partly through the issuance of a warrant to purchase 50,000 shares of common stock at $1.10 per share that vested immediately and expires in three years. The fair value of the warrant, using the Black–Scholes option pricing model was $11,329. The weighted-average assumptions used to determine the fair value of the warrants were as follows: risk-free interest rate of 4.23%; warrant life of 3 years; dividend yield of 0% and expected volatility of 70%. In connection with these services, $10,825 and $504 was charged to operations for the years ended December 31, 2006 and December 31, 2005, respectively.

In January 2006, the Company entered into an agreement with an investor relations firm to provide services and was subsequently cancelled. The Company issued warrants to purchase 50,000 shares of common stock at $1.10 per share that will expire in three years. The fair value of warrants was $14,524 based on the Black Scholes option pricing model and was charged to expense. The weighted average assumptions used to determine fair market value of the warrants are as follows: interest rate of 4.34%, expected warrant life of 3 years, dividend yield of 0% and expected volatility of 70%.

In June 2006, the Company issued to a consultant for research and development services to be rendered through March 31, 2007, warrants to purchase an aggregate of 225,000 shares of common stock at an exercise price of $0.62 per share and which expire in seven years. Warrants to purchase 100,000 of these shares vested on the date of issuance and the remainder will vest only if the consultant satisfies a milestone performance obligation as specified in the consultant's agreement. In addition, a maximum of 80,000 additional warrants will be granted to this consultant in the event he satisfies additional performance milestones. The consultant was paid $100,000 in February 2007 for achieving a milestone as defined in the consulting agreement. Such balance was accrued as of December 31, 2006. The Company valued the 100,000 vested warrants at $43,879 based upon the Black Scholes option pricing model. The weighted average assumptions used to determine fair market value of the warrants is as follows: interest rate of 5.23%; expected warrant life of 7 years; dividend yield of 0% and expected volatility

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE I – STOCKHOLDERS EQUITY (CONTINUED)

[2] Warrants (continued):

of 149%. In September 2006, the Company recorded the value of 125,000 unvested warrants at $85,297 based upon the Black Scholes option pricing model related to the performance condition because the Company deemed it probable that the performance criteria would be met. The weighted average assumptions used to determine fair market value of the warrants is as follows: interest rate of 4.60%; expected warrant life: 7 years; dividend yield of 0% and expected volatility of 138%. In addition, the Company incurred $194,000 of expenses related to this agreement through December 31, 2006 which includes $100,000 for the expected milestone. For subsequent periods, the value of the warrant will be credited or charged to the Consolidated Statement of Operations at each reporting period to reflect subsequent changes in value until the milestone has been met. If the milestone has not been met, then cumulative charges will be credited to income in the Consolidated Statement of Operations.

In December 2006, the Company recorded an expense for the issuance of an additional 125,000 warrants relating to the June 2006 grant for research and development services for the attainment of a performance condition. The additional expense recorded upon reaching the vesting criteria in December 2006 was $49,122 and the aggregated expense was $134,419. The weighted average assumptions used to determine fair market value of the warrants is as follows: interest rate of 4.54%, expected warrant life: 7 years; dividend yield of 0% and expected volatility of 133.46%.

On November 2, 2007, the Company and its wholly-owned subsidiary, Lev Development Corp. entered into a Term Loan Agreement dated as of November 2, 2007 (the "Loan Agreement") and a Pledge and Security Agreement of the same date (the "Security Agreement" and together with the Loan Agreement, the "Secured Financing Agreements"), among the Company, the Lender executing the Loan Agreement (the "Lender") and Mast Capital Management, LLC, as agent for the Lender. In connection with the Loan Agreement with Mast (see Note G), the Company issued Mast warrants to purchase an aggregate of 900,000 shares of Company common stock. The Warrants are for a term of three years and have an exercise price of $1.6576 per share, which is the volume weighted average price per share of the Company's common stock for the thirty trading days immediately preceding the closing. The Company also entered into a registration rights agreement with the Lender pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock which may be issued upon exercise of the Warrants upon the demand of the holders of a majority of the Warrants. If no registration statement is filed and declared effective by the Securities and Exchange Commission covering the resale of the shares of common stock which may be issued upon exercise of the Warrants, the lender may exercise the warrants for unregistered shares of common stock. The Company valued the warrants at $1,098,019 using the Black Scholes option pricing model and is deemed a debt discount. The debt discount is netted against the term loan and amortized over the life of the loan and is charged to interest expense. The assumptions used to determine the fair value of the warrants are as follows: risk-free interest rate of 3.68%; expected warrant life of 3 years; dividend yield of 0% and expected volatility of 107%.

The weighed average fair value at the date of grant for warrants granted during the years ended December 31, 2007, 2006 and 2005 was $1.22, $0.70 and $0.26, respectively, using the Black-Scholes pricing option model.

Warrant activity is summarized as follows:

	Shares	Weighted-Average Exercise Price
Warrants outstanding and exercisable as of December 31, 2004	301,668	$ 0.38
Granted (1)	3,555,099	$ 1.24
Exercised (2)	(190,327)	$ 0.04
Cancelled (1)	(301,668)	$ 0.38
Warrants outstanding and exercisable as of December 31, 2005	3,364,772	$ 1.31
Granted	11,864,365	$ 0.84
Warrants outstanding and exercisable as of December 31, 2006	15,229,137	$ 0.95
Granted	5,566,667	$ 1.83
Exercised	(406,633)	$ 1.35
Warrants outstanding and exercisable as of December 31, 2007	20,389,171	$ 1.18

(1) Includes repriced warrants of 301,668, see Note I.
(2) Exercised on a cashless basis for a net share issuance of 179,451 shares in September, 2005.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE I – STOCKHOLDERS EQUITY (CONTINUED)

[2] Warrants (continued):

The following table summarizes information about warrants outstanding at December 31, 2007:

Exercise Price	Number Outstanding And Exercisable	Weighted Average Remaining Contractual Life (In Years)
$ 0.30 - $0.62	336,341	6.1
$ 0.84	11,390,846	3.8
$ 1.10 - $1.18	298,519	1.9
$ 1.35	2,796,798	2.4
$ 1.66	900,000	2.8
$ 1.86	4,666,667	4.6
	20,389,171	

NOTE J - COMMITMENTS AND CONTINGENCIES

[1] Sanquin Blood Supply Foundation:

Sanquin Blood Supply Foundation ("Sanquin") is an Amsterdam-based not-for- profit organization that provides blood and plasma products and related services, and carries out research and education in the Netherlands. The Company has a series of agreements (the "Sanquin Agreements") with Sanquin, including an option agreement, a distribution and manufacturing services agreement and a license agreement. The Sanquin Agreements are intended to allow the Company to conduct clinical trials of the C1-INH (the "Product") manufactured and supplied by Sanquin, and to sell the Product following regulatory approval.

(a) Option agreement:

In September 2003, the Company and Sanquin entered into an option agreement (the "Option Agreement") under which Sanquin granted to the Company an option for an exclusive, world-wide license to certain Sanquin technology and underlying patents. The Company paid Sanquin a non-refundable fee of $25,000 in exchange for the rights to this option. In January, 2004, the Company exercised its option under the Option Agreement (see License Agreement below).

(b) Distribution and manufacturing services agreement and loan receivable:

In January 2004, the Company and Sanquin entered into a distribution and manufacturing services agreement (the "Distribution Agreement") under which Sanquin agreed to manufacture and supply agreed-upon quantities of the Product to the Company, as soon as Sanquin obtained an export license during 2005, for an agreed-upon minimum price, which is subject to change. In connection with quantities supplied for the clinical trial prior to regulatory approval, Sanquin has provided a loan to the Company in the amount of the Product purchased, which is subject to a purchase money security interest in the Product. Upon regulatory approval, Sanquin will forgive the loan and release any and all security interests. If regulatory approval is not obtained, the loan is payable on January 16, 2014 or on cancellation of the Distribution Agreement. Title to the Product transfers to the Company upon delivery. The Product is being used to conduct Phase III clinical trials. Sanquin also granted to the Company the exclusive right to distribute, market and sell the Product in the U.S. and certain other countries, upon receiving regulatory approval to do so in each respective country.

On June 1, 2007 the Company exercised an option to extend the Distribution Agreement. The Distribution Agreement with Sanquin terminates on December 31, 2010, unless extended by the Company for up to a three-year period or by mutual agreement of the parties prior to its expiration.

On October 10, 2007, the Company entered into an amendment, dated as of September 24, 2007, to the Distribution Agreement. Pursuant to the amendment, the Company agreed on terms of a construction project to scale-up the production facilities of

[1] Sanquin Blood Supply Foundation (continued):

Sanquin to be used for the purpose of meeting the Company's anticipated ongoing requirements for the commercial use of the C1-INH product to be marketed as Cinryze™. Pursuant to the terms and conditions of the amendment, the Company will develop a project plan for the construction to the production facilities with Sanquin. Subject to the terms of the final project plan, the Company will provide Sanquin with a non-interest bearing loan, up to a maximum amount of €7.5 million (approximately US $11.0 million, based on the exchange rate as of December 31, 2007), to finance the construction project. This loan will be due July 1, 2014 and Sanquin agreed to repay the principal amount of the loan by providing us with a discount to the per unit purchase price of Cinryze™. The loan receivable balance outstanding as of December 31, 2007 was $3,414,755 and the fair value of the loan was $3,064,186. In accordance with APB No. 21, interest on receivables and payables, the Company did not impute interest since the loan does not require repayment in the future, but rather will be applied to the purchase price of Cinryze™. The estimated fair value of the loan receivable is based on the present value of the cash flows discounted at a rate (5.5%) that approximates current market returns. In addition, in the event the agreement is terminated before July 1, 2014 because of a default by the Company or if by such date the volume of product the Company ordered is less than the required volume for Sanquin to repay the loan, then the Company shall waive the then outstanding balance of the loan.

Pursuant to the amendment, Sanquin shall manufacture C1-INH product for the Company on a toll-manufacturing basis using blood plasma supplied by the Company. The Company agreed to purchase a specified amount of such product from Sanquin totaling approximately $19.1 million until the scale up is approved by the appropriate regulatory authorities, which we expect to occur during 2009. In addition, the Company agreed to an annual minimum purchase commitment of product of approximately $21.7 million during the term of the Agreement commencing in the year in which the scale up is approved in the U.S. for commercial production. The Company and Sanquin agreed to negotiate in good faith to modify these requirements in the event that regulatory approval for commercial release of Cinryze™ in the U.S. does not occur by March 31, 2008. The Company's contractual purchase commitments are subject to annual adjustments based on market conditions and do not include the cost of storage, handling and testing services that Sanquin will provide.

(c) License agreement:

In January 2004, the Company obtained an exclusive world-wide license agreement (the "License Agreement") with Sanquin, thus exercising its option under the Option Agreement. The Company has the right to grant sub-licenses under the License Agreement. The License Agreement gives the Company the right to perform research for, make, use and sell the licensed technology and licensed products, as defined.

In consideration for the granting of the license, the Company agreed to pay Sanquin, within 60 days of execution of the License Agreement, $82,000, the agreed-upon amount of expenses incurred by Sanquin for the preparation, filing and maintenance of the underlying patents through the date of execution of the License Agreement. In addition, the Company shall make the following payments to Sanquin during the course of the License Agreement: (i) royalties on net sales, as defined, of therapeutic products or diagnostic products, as defined; (ii) a non-refundable, non-creditable one-time license access fee of $175,000 within 60 days of execution of the License Agreement; (iii) minimum annual royalties beginning in the first year of commercialization, as defined; and (iv) 10% of the consideration received from patent infringement settlements. In addition, the Company is required to create a comprehensive research plan for the commercial exploitation of the licensed technology. The Company is continuing to work with Sanquin on the design of the research plan for AMI. The Company agreed to commit a minimum of $125,000 per annum during the first three years following the execution of the License Agreement toward research on the licensed technology conducted by Sanquin and other parties. In February 2004, the Company paid $257,000 in connection with execution of the License Agreement and such amounts were recorded in the Consolidated Statement of Operations for the year ended December 31, 2004 as research and development expense.

The License Agreement will terminate upon the expiration of the last to expire patent underlying the related technology. In the event of expiration of the License Agreement, the Company will have a royalty-free, fully paid-up, non-exclusive license to the technology. Either party may terminate the License Agreement upon breach by the other party that is not cured within 30 days of written notice. The Company will have the right to terminate the License Agreement for any reason, with 90 days written notice to Sanquin at which time the Company will be responsible to pay certain defined outstanding obligations. Sanquin may terminate the License Agreement if the Company does not perform, as defined, under the License Agreement and such failure to perform is not cured within 60 days after written notice to the Company.

[2] Plasma agreement:

On July 19, 2007, the Company entered into an agreement, for the purchase and sale of plasma with DCI Management Group, LLC (the "DCI Agreement") pursuant to which the Company will purchase certain quantities of U.S. Source Plasma to be utilized in the production of product under our Distribution and Manufacturing Services Agreement with Sanquin. Under the DCI Agreement, the supplier agreed to sell us specified annual quantities of plasma, in accordance with applicable good manufacturing practices. In 2007, the Company purchased approximately $13.5 million of plasma under this agreement. The Company is committed to purchase $13,950,000 worth of product during 2008. Thereafter the Company expects its annual purchase commitment to be between $12.2 million and $12.9 million for the balance of the term of the DCI Agreement. The Company's contractual purchase commitments are subject to annual percentage increases based on market conditions. The Company anticipates its total commitment under this DCI Agreement to be approximately $51.7 million.

The DCI Agreement expires December 31, 2011, unless sooner terminated in accordance with its terms. Either party may terminate the DCI Agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable cure periods. Subject to the supplier's ability to mitigate damages, in the event the Company is in default of its payment obligation under the contract, the Company will be liable to purchase the minimum quantities of plasma specified under the contract for the balance of the term. The Company has the right, however, to terminate the contract if by December 31, 2008 the Company does not obtain regulatory approval for the commercialization of its lead product candidate or are not able to secure adequate financial arrangements to cover our obligations with respect to the initial purchase commitments under the DCI Agreement. In either such event, the Company will be obligated to complete the purchase of 80% of the initial minimum purchase commitment, subject to the supplier's ability to mitigate damages. Upon expiration of the DCI Agreement, or in the event the DCI Agreement is terminated for reasons other than as set forth above, the Company will be obligated to purchase a closing inventory of plasma in the quantity specified in the DCI Agreement.

[3] Service agreements:

In March, 2005, the Company entered into an agreement with a clinical research organization ("CRO") for the design, management and implementation of clinical development programs. Based on existing commitments, the estimated fees for the services to be provided as of December 31, 2007 are approximately $567,000. No assurances can be given that the total fees we incur under this agreement will not exceed the Company's estimates. Approximately $1,214,000, $687,000 and $419,545 have been incurred for the years ended December 31, 2007, 2006 and 2005, respectively. The Company entered into a separate service agreement with the CRO in September 2006 which governs the CRO's provision of additional services in connection with the Company's Phase III clinical trials and activities related to the commercialization of the Company's product candidates. Pursuant to the September 2006 service agreement, the Company entered into three separate work orders, each pertaining to following aspects of the Phase III clinical trials: open label prophylaxis treatment of HAE, pharmacokinetics and open label acute treatment of HAE. The services provided by the CRO pursuant to both contractual arrangements are on a work order basis and the Company is invoiced on time and materials basis. The Company has the right to terminate both contracts, and any pending work order, on prior notice and without cause.

[4] Operating lease:

On October 25, 2006, the Company entered into a month-to-month lease for office space for its New York City location. On September 25, 2006, the Company entered into a lease agreement for one-year for its office space in the metropolitan area of Philadelphia, Pennsylvania. This lease agreement was amended on August 7, 2007 for an additional one year term. The Company utilized space provided by founders/officers and certain of its employees without remuneration. During the years ended December 31, 2007, 2006 and 2005, rent expense was $242,369, $78,575 and $60,166, respectively before sublease income. In addition, the Company had sublet a portion of its New York City office space to third parties on a month-to-month basis. Rental income from this sublease amounted to $0, $20,691 and $28,065 for the years ended December 31, 2007, 2006 and 2005, respectively. On December 20, 2006, the Company entered into a new lease for office space for its New York City location that expires in January 2012. In connection with this lease, the Company entered a letter of credit for $93,335 that is collateralized by a certificate of deposit.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE J - COMMITMENTS AND CONTINGENCIES (CONTINUED)

[4] Operating lease (continued):

Future minimum rental payments under operating leases are as follows:

Year Ending December 31,	Operating Lease
2008	$ 245,000
2009	199,000
2010	205,000
2011	209,000
2012	51,000
Thereafter	0
Total	$ 909,000

[5] Employment Agreements:

On November 1, 2004, the Company entered into employment agreements (the "Employment Agreements"), expiring on October 31, 2008 (the "Initial Term"), with the Chief Executive Officer and with the Chairman and Executive Vice President of the Company (the "Executives"), who are also significant stockholders of the Company. Under the terms of the Employment Agreements, the Executives each receive annual base compensation of $312,500, (increased to $344,531 on November 1, 2006) which will increase every year by the greater of 5% or the percentage increase of the Labor Consumer Price Index, and fully vested options to purchase 1,427,450 shares of the Company's common stock exercisable at $0.85 per share, which will expire on November 1, 2014. Under the provisions of the Employment Agreements, the Executive will receive a cash payment equal to their salary for the remainder of the term of the Employment Agreements upon any occurrence of a change in control of the Company, as defined in the Employment Agreements. The Employment Agreements will be automatically renewed for additional one-year periods (the "Renewal Terms") unless either party notifies the other in writing of its intention not to renew within 90 days prior to the expiration of the Initial Term or any Renewal Terms (the Initial Term together with the Renewal Terms are referred to as the "Term"). Upon termination, as defined in the Employment Agreements, the Executives will continue to receive compensation through the end of the current Term, unless such Term is reduced.

On January 23, 2007, the Company entered into amended and restated employment agreements with each of its Chief Executive Officer, Mr. Joshua D. Schein, and its Executive Vice President and Chairman, Mr. Judson Cooper. Both employment agreements are effective as of January 17, 2007. Under the employment agreements, the Executives will be entitled to a base salary of $425,000 beginning as of January 1, 2007. In addition, the Executives are entitled to a bonus as defined in the employment agreements. The Executives were each granted options to purchase 1,600,000 shares of the Company common stock, which options expire ten years from the date of grant and which are exercisable at an exercise price of $1.60, which was equal to the closing price of its common stock on the date of grant (January 17, 2007). The options vest in equal annual installments of 25% of the total option amount until vested in full, subject to the terms and conditions of the Company's 2004 Omnibus Incentive Compensation Plan. In the event of the termination of employment by the Company without "cause" or by an Executive for "good reason," there is a lump sum settlement payable as defined in the employment agreements. There is a provision for payment of additional benefits in the event of a change of control.

On December 20, 2007, the Company entered into a second amended and restated employment agreements with each of its Chief Executive Officer, Mr. Joshua D. Schein, and its Executive Vice President and Chairman, Mr. Judson Cooper. In addition to the execution of the amended and restated employment agreements, on December 20, 2007, we also awarded each of the Executives a cash bonus for the 2007 fiscal year of $425,000, which was approved by our Compensation Committee. The amended and restated employment agreements are for an initial term expiring December 31, 2012 and at the end of the initial term renew automatically for additional one year terms unless sooner terminated or not renewed. Under the employment agreements, the Executives will continue to receive a base salary of $425,000; provided, however, that the base salary shall increase to $500,000 effective upon the date on which the U.S. Food and Drug Administration approves our biologics license application for its lead product candidate (the "Approval Date"). In addition, the base salary shall increase at the end of each year of service (commencing at the end of 2007) by the greater of (i) 4% or (ii) a percentage equal to the increase, if any, in the United States Department of Labor Consumer Price Index (or comparable index, if available) for the New York metropolitan area over the previous 12 months. Commencing in the year in which the Approval Date occurs, the Executives will be entitled to a bonus opportunity within the target range of 75% to 200% of base salary, based on satisfaction of performance targets to be determined by the Compensation Committee. In addition, we granted 2,000,000 shares of restricted common stock to each of

[5] Employment Agreements (continued):

the Executives with the following vesting schedule: 50% of the restricted stock shall vest and the restrictions thereon shall lapse on the Approval Date and thereafter 25% of the restricted stock shall vest and the restrictions thereon shall lapse on each of the first and second anniversaries of the United States Food and Drug Administration Approval Date. The Company has determined that it is probable as of December 31, 2007 that the restricted shares will be vested. The Company cannot provide any assurances as to when it may receive FDA approval and in the event that FDA approval is not obtained by such date, the Company will revise its estimates regarding these awards. Therefore, the Company recorded compensation expense of $184,643 for the period December 20, 2007 to December 31, 2007 based upon the value of the common stock amortized through the estimated approval date.

Effective March 16, 2007, the Company entered into an employment relationship with Mr. Dov S. Elefant for Mr. Elefant to serve as its Corporate Controller. Pursuant to the terms of an offer letter executed by the Company and Mr. Elefant, Mr. Elefant will serve as Corporate Controller on an at-will basis and earn an annual salary at the rate of $195,000. Mr. Elefant will be eligible for an annual bonus of $20,000 in the discretion of the compensation committee of the Board. In the event Mr. Elefant's employment is terminated by the Company without cause within three years of his start date, the Company will pay him a severance payment of six months of his then-current base salary. In addition, pursuant to the Company's 2004 Omnibus Incentive Compensation Plan and subject to the terms and conditions therein, on March 19, 2007, the Company granted Mr. Elefant options to purchase 200,000 shares of the common stock, which options are exercisable for a period of seven years at a per share price of $1.75 and which options vest over a three year period, with 1/3 of the option award vesting on the one-year anniversary of the date of grant and the balance vesting in equal monthly installments of 1/24 of the remaining option award over the following 24 months.

The Company entered into employment agreements with its Chief Financial Officer ("CFO") and Vice President - Regulatory Affairs and Product Development, on June 7, 2006 for two and three year terms, respectively. The Company's CFO will receive an annual base salary of $175,000 for the initial year and increasing to $183,500 for the second year. The CFO was granted options to purchase 125,000 shares of common stock at an exercise price of $0.50 per share, the fair market value at the date of grant, 62,500 options vest on the first anniversary date of the grant and the remainder vests on the second anniversary of the grant. The Company's Vice President - Regulatory Affairs and Product Development will receive an annual base salary of $200,000 during the term of the agreement which was increased to $230,000 in December 2007, and will be entitled to an annual bonus of $20,000 on each anniversary date. In addition, our Vice President- Regulatory Affairs and Product Development was granted options to purchase 500,000 shares of the Company's common stock at an exercise price of $0.50 per share, the fair market value at the date of grant, which options vest as follows: 100,000 shares vest on the commencement date of the employment agreement, 300,000 shares shall vest equally over three years and 100,000 shares shall vest upon the occurrence of the milestone event specified in the employment agreement. The option agreements contain a provision for payment of certain benefits in the event of a change of control. The employment agreements provide for a severance payment if the employee is terminated without cause.

The Company entered into an at-will employment agreement with its Vice President - Marketing and Sales on August 2, 2006. Pursuant to this agreement, the Company's Vice President - Sales and Marketing receives an annual base salary of $240,000 during the term of the agreement which was increased to $247,200 effective July 31, 2007 and will be eligible to receive an annual bonus of up to 35% of the base salary subject to his attainment of performance criteria to be approved by the Board. In addition, the Company awarded the Vice President - Sales and Marketing a one-time signing bonus of $30,000 upon the execution of the employment agreement. In connection with the employment agreement, the Vice President - Sales and Marketing was granted options to purchase 600,000 shares of the Company's common stock at an exercise price equal of $0.65 per share, the fair value at the date of grant. These options vest as follows: 200,000 shares vest on the commencement date of the employment agreement, and options to purchase an additional 400,000 shares shall vest in equal amounts of 100,000 on each of the first four anniversary dates of the commencement date. The option agreement provides for a change of control provision. The employment contract provides for a severance payment if the employee is terminated without cause.

[6] Legal:

The Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not presently a party to any proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on our business, results of operations or financial condition.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE K - STOCK OPTIONS AND WARRANTS:

In March, 2004 (the "Effective Date"), the Company's Board and stockholders adopted the 2004 Omnibus Incentive Compensation Plan (the "Plan"). The Plan has been adopted as a means of attracting, motivating, and retaining the best available personnel for positions of substantial responsibility within the Company, and in order to provide additional incentive to directors, employees, and other eligible individuals (the "Awardees"). Under the Plan, the initial maximum number of options to acquire shares of the Company's common stock that were available for issuance to Awardees was 3,500,000.

Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined. The Plan provides for the Board or a Committee of the Board (the "Committee") to grant Awards to Awardees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the Awards, including acceleration of the vesting of an Award at any time. All options granted under the Plan are intended to be non-qualified ("NQO") unless specified by the Committee to be incentive stock options ("ISO"), as defined by the Internal Revenue Code. NQOs may be granted to employees, consultants or other individuals at an exercise price, equal to, below or above the fair value of the common stock on the date of grant. ISOs may only be granted to employees of the Company and may not be granted at exercise prices below fair value of the common stock on the date of grant (110% of fair value for employees who own 10% or more the Company). Under the Plan, following the termination of an Awardee's employment or active involvement with the Company, the Committee shall determine the extent to which the Awardee has the right to exercise outstanding options. The Plan will terminate at the earliest of (i) its termination by the Committee or (ii) March 18, 2014. Awards granted before termination of the Plan will continue under the Plan until exercised, cancelled or expired.

On December 29, 2004, the Company increased the number of shares available for issuance under the Plan from 3,500,000 to 10,000,000. In addition, on such date the Company issued options to purchase 675,000 shares of common stock under the Plan to three directors at an exercise price of $0.80 per share that vest equally over three years. On March 11, 2005, the Company issued options to purchase 100,000 shares of stock under the Plan to its Chief Financial Officer at an exercise price of $1.20 that vest equally over two years.

Following the merger between Lev and a subsidiary of FCP, in May 2005 the Company's Board of Directors determined that the basis for the exchange of options and warrants to purchase common stock of Lev outstanding prior to the merger for options and warrants to purchase common stock of the Company should be changed. Though the number of shares issuable upon exercise of these options and warrants was increased, the parties to the merger did not proportionately reduce the exercise price of these options and warrants to account for the increase in the number of shares outstanding after the merger. Accordingly, in May 2005, the exercise price of outstanding warrants to purchase 190,327 shares was reduced from $0.10 to $0.04 per share. Also, the exercise price of outstanding warrants to purchase 111,341 shares was reduced from $0.85 to $0.30 per share. At the date of this repricing, the Company recognized a charge to the Statement of Operations of $27,819 for the incremental fair values of these warrants using the Black-Scholes option pricing model. The weighted-average assumptions used to determine the fair values of the warrants are as follows: risk-free interest rate of 3.83%; expected warrant life of 3 years; dividend yield of 0% and expected volatility of 70%.

In July 2005, the Board further determined to obtain stockholder approval on December 12, 2005, to reduce the exercise price, from $0.85 to $0.30, of outstanding options to purchase 1,427,450 shares of common stock held by each of the Chief Executive Officer and the Chairman, respectively (an aggregate of 2,854,900 shares). The stockholders approved the repricing. The Company recorded a charge to the Consolidated Statement of Operations at the repricing date and at each reporting date, based upon subsequent changes in values of the price of Company's stock and recorded an aggregate charge for these employee stock options of $1,427,450.

As of December 31, 2007, there are 15,100 options available to grant under the Plan.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE K - STOCK OPTIONS AND WARRANTS (CONTINUED):

The following table summarizes information about stock options under the Plan outstanding as of December 31, 2007:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Number Exercisable
$0.30	2,854,900	6.8	2,854,900
$0.50	625,000	8.4	362,500
$0.63	40,000	5.6	40,000
$0.65	600,000	8.6	300,000
$0.69	300,000	8.7	100,000
$0.80	675,000	7.0	675,000
$0.90	300,000	5.8	100,000
$0.95	100,000	5.8	33,333
$1.20	100,000	7.2	100,000
$1.60	3,460,000	7.6	
$1.63	300,000	9.1	
$1.64	10,000	6.3	
$1.75	495,000	6.2	
$1.80	10,000	6.1	
$1.85	115,000	6.1	
	9,984,900		4,565,733

The following table summarizes information about stock options outside the Plan outstanding as of December 31, 2007:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Number Exercisable
$1.76	800,000	6.9	50,000
$1.86	1,265,273	6.9	70,000
$1.94	100,000	6.9	
	2,165,273		120,000

NOTE L - INCOME TAXES

There is no provision (benefit) for federal or state income taxes for the years ended December 31, 2007 and 2006 since the Company has incurred operating losses and has established a valuation allowance equal to the total deferred tax asset.

The tax effect of temporary differences and net operating losses as of December 31, 2007 and 2006 are as follows:

	2007	2006
Deferred tax asset and valuation allowance:		
Research and development cost	$9,554,000	$ 4,245,000
Research and development credits	1,261,000	525,000
Net operating loss carryforwards	7,987,000	3,525,000
Options and warrants	1,815,000	817,000
Contributions	233,000	141,000
Other	176,000	70,000
Total deferred tax asset	21,026,000	9,323,000
Valuation allowance	(21,026,000)	(9,323,000)
Net deferred tax asset	$ 0	$ 0

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE L - INCOME TAXES (CONTINUED):

At December 31, 2007, the Company has available, for tax purposes, unused net operating loss carryforwards of approximately $20,378,000 that expire from 2023 to 2027. The Company has approximately $1,261,000 of research and development credits that expire from 2024 to 2027. The increase to the valuation allowance from December 31, 2006 to 2007 was $11,703,000 and the increase in valuation from December 31, 2005 to 2006 was $4,522,000. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the Company's net operating loss and credit carryforwards prior to December 4, 2007 and August 23, 2004 was limited due to a cumulative change in ownership of more than 50% that occurred within a three-year period.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any uncertain income tax positions.

The Company's 2003 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

A reconciliation of the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax provision is as follows:

	December 31,		
	2007	2006	2005
Statutory federal income tax rate	(34) %	(34) %	(34) %
State income tax rate, net of federal taxes	(0)	(0)	(0)
Permanent difference	0.1	0.2	0.3
Valuation allowance	33.9	33.8	33.7
Income tax provision	0 %	0 %	0 %

NOTE M – RELATED PARTIES

In March 2004, the Company entered into a consulting agreement with Richard Stone and granted to Mr. Stone a fully vested warrant in consideration for assisting us in developing the Company's strategic business plan, obtaining the Sanquin license and consulting on our corporate structure. The warrant was for the purchase of 7,137,249 shares of common stock at an exercise price of $0.10 per share, expiring in March 2014; see Note I [2]. The fair value of the warrant using the Black-Scholes option-pricing model was approximately $1,934,000. On August 23, 2004, Mr. Stone exercised these warrants on a "cashless exercise" transaction pursuant to which we issued a total of 6,297,571 shares of common stock. On April 1, 2005, the Company entered into a one year consulting agreement commencing April 1, 2005 with Richard Stone. The Company renewed this agreement with Mr. Stone in April 2006 and April 2007. Mr. Stone is paid $120,000 per year for his services, with payments made quarterly. Mr. Stone beneficially owns more than 5% of the Company's outstanding common stock.

As described in greater detail in Note H to these financial statements, on November 2, 2007, the Company and its wholly-owned subsidiary, Lev Development Corp. entered into a Term Loan Agreement dated as of November 2, 2007 (the "Loan Agreement") and a Pledge and Security Agreement of the same date (the "Security Agreement" and together with the Loan Agreement, the "Secured Financing Agreements"), among the Company, the Lender executing the Loan Agreement (the "Lender") and Mast Capital Management, LLC ("Mast"), as agent for the Lender. In connection with this arrangement, the Company paid Richard Stone $100,000 which was a 1% fee of the amount borrowed. In addition, on February 11, 2008, the lender, agent for the lender and two affiliated individuals filed a Schedule 13G with the Securities and Exchange Commission reporting that as of January 30, 2008, such persons were the beneficial owner of greater than 5.0% of the Company's common stock. Accordingly, in the event that the Company elects to increase its borrowings under this loan arrangement, such transaction would be reviewed by the audit committee of the Company's board of directors in accordance with its procedures for reviewing related party transactions.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE N – UNAUDITED QUARTERLY RESULTS

Summarized quarterly results of operations for the years ended December 31, 2007 and 2006 are as follows:

	Year Ended December 31, 2007			
	First	Second	Third	Fourth
Operating expenses	$ 5,645,090	$ 6,987,158	$ 7,438,380	$ 8,419,651
Other income/(expense), net	167,017	94,032	185,089	(37,285)
Net loss	$ (5,478,073)	$ (6,893,126)	$ (7,253,291)	$ (8,456,936)
Net loss per share – basic and diluted	$ (0.05)	$ (0.06)	$ (0.06)	$ (0.06)
Weighted average shares – basic and diluted	114,046,749	114,157,528	125,576,290	137,750,203

	Year Ended December 31, 2006			
	First	Second	Third	Fourth
Operating expenses	$ 1,850,037	$ 1,950,005	$ 2,556,244	$ 5,646,617
Other income/(expense), net	36,512	27,110	7,539	164,253
Net loss	$ (1,813,525)	$ (1,922,895)	$ (2,548,705)	$ (5,482,364)
Net loss per share – basic and diluted	$ (0.02)	$ (0.02)	$ (0.03)	$ (0.05)
Weighted average shares – basic and diluted	81,527,544	81,638,377	81,702,544	107,856,364

Independent Board of Directors

Henry M. Dachowitz
Former Treasurer, Nassau County, NY

Scott Eagle
Chief Operating Officer, Claria Corporation

Thomas Lanier
U.S. Department of the Treasury

Eric I. Richman
Senior Vice President, Business Development and Strategic Planning, PharmAthene, Inc.

Executive Officers

Judson A. Cooper
Chairman and Executive Vice President

Joshua D. Schein, Ph.D.
Director and Chief Executive Officer

Douglas J. Beck
Chief Financial Officer

Dov Elefant
Corporate Controller

Senior Management

Matthew Duffy
SVP, Commercial Operations

Jason Bablak
VP, Regulatory Affairs and Product Development

Bart Jones
VP, Sales

Ira N. Kalfus, M.D.
VP, Medical Affairs

Joseph Truitt
VP, Business Development & Product Strategy

Corporate Headquarters

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Annual Meeting

May 15, 2008, at 10:00 a.m.
The W Hotel
541 Lexington Avenue
New York, NY 10022

Independent Registered Public Accounting Firm

Eisner LLP
750 Third Avenue
New York, NY 10017

Investor Relations

Shareholders and members of the investment community may direct their inquiries to:

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45 Broadway, 11th Floor
New York, NY 10006

Stock Listing

Lev's common stock is traded on the OTC Bulletin Board under the ticker symbol: LEVP

Transfer Agent

Securities Transfer Corp.
2591 Dallas Parkway Suite 102
Frisco Texas 75034
(469) 633-0101

END

Annual Report on Form 10-K

This Annual Report contains the Annual Report on Form 10-K for fiscal 2007, as filed with the Securities and Exchange Commission. Additional copies of this Annual Report may be obtained without charge by contacting our Investor Relations department, or over the Internet. For shareholder communications regarding change of address, transfer of share ownership or lost certificates, please contact our Transfer Agent.