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Anesiva 2007 Annual Report



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# CHANGING THE FACE OF PAIN

  
Anesiva



## T O O U R S T O C K H O L D E R S

### **Dear Stockholders:**

2007 was a defining year for Anesiva. We achieved the goals we set out at the beginning of the year, significantly advancing both of our product franchises and building a commercial infrastructure for the launch of our first pain therapeutic. We also strengthened our company's focus with the hiring of key individuals with deep experience in pain management.

We're pleased to review with you our progress and achievements:

### **Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system: Preparing for commercial introduction**

Zingo is Anesiva's easy-to-administer, single-use, needle-free system that delivers sterile lidocaine powder into the skin and provides topical, local analgesia. Its rapid onset of action allows IV placement or venipuncture to begin one to three minutes after administration.

In August, Zingo was approved by the U.S. Food and Drug Administration (FDA) to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. More than 18 million pediatric peripheral venous access procedures are performed in U.S. hospitals each year. We have planned extensively for Zingo's launch to ensure successful marketing, sales and manufacturing.

In February 2008, we deployed an experienced 15-person hospital-based sales force, under seasoned leadership, to educate healthcare providers about Zingo. We also signed an agreement to co-promote Zingo in the United States with Sagent Pharmaceuticals, forging what we believe is a truly synergistic partnership.

Our marketing team implemented several awareness initiatives to improve peripheral venous access pain management in children, including a website tailored to healthcare professionals and parents, [www.ManageIVPain.com](http://www.ManageIVPain.com), and RN VOICE (Registered Nurses for Venipuncture Optimization through Increased Comfort and Education), a multidisciplinary organization founded to facilitate better management of pediatric venous access pain.

To maximize Zingo's global market opportunity, we forged an exclusive licensing agreement with experienced partner Sigma-Tau SpA covering major European markets, and we granted an exclusive license to Medical Futures, Inc. for marketing and distribution of Zingo in Canada.

**“More than 18 million pediatric peripheral venous access procedures are performed in U.S. hospitals each year. We have planned extensively for Zingo's upcoming launch to ensure successful marketing, sales and manufacturing.”**

In the U.S., with FDA approval for Zingo's pediatric indication in hand, we recently filed a supplemental New Drug Application to expand the label to include adults, who undergo approximately 400 million peripheral venous access procedures each year in U.S. hospitals.

In 2008, we'll work to grow the Zingo franchise through our innovative marketing and sales efforts while taking steps to ensure manufacturing capacity sufficient to meet product demand.

#### **Adlea™: Blockbuster Potential**

Adlea is a potent, long-acting, non-opioid analgesic drug candidate designed to provide pain relief for weeks to months after a single local application. Adlea has been evaluated in multiple clinical trials that have demonstrated its ability to provide site-specific, local pain relief without most of the systemic side effects associated with currently opioid-based pain medications and other analgesics such as NSAIDs.

Adlea has demonstrated long-lasting pain reduction in Phase 2 trials to date. Treatment with Adlea, which is non-addictive and non-narcotic, may reduce the need for other, less safe, systemic pain medications. Further, in highly painful circumstances such as total knee replacement surgery, Adlea can be additive to existing therapies to provide long-lasting post-operative pain relief.

**“Adlea has demonstrated long-lasting reduction in pain in Phase 2 trials to date.”**

We're working to develop Adlea in indications with high unmet need, focused initially on clinical trials supporting an approval to manage pain following orthopedic surgery. We currently have underway two pivotal Phase 3 trials, one in bunionectomy surgeries and one in total knee replacement surgeries, and anticipate having data from these trials by the end of this year.

We also have initiated multiple Phase 2 trials over the last year for post-operative pain associated with orthopedic surgeries, including total hip replacement and knee replacement surgeries. Efficacy data are already available in additional surgical indications including total knee replacement, tendonitis and bunionectomy.

Adlea also has tremendous potential for treating pain associated with moderate to severe osteoarthritis. Exploratory studies have demonstrated that Adlea provides pain relief for weeks to months in patients suffering from osteoarthritis of the knee. A Phase 2 trial for this indication is ongoing.

We're working to bring Adlea through development swiftly, as we believe its superior profile and utility across indications make it a potential blockbuster. We are pursuing partnerships that may support the development and commercialization of Adlea in multiple indications.

**Looking ahead: Growing our value**

While we accomplished a great deal in 2007 to transform Anesiva into a company poised to commercialize Zingo, we also put in place an infrastructure for the sales and marketing of potential future products such as Adlea. We worked to support this infrastructure in 2007 by completing a \$47.7 million financing, finishing 2007 with \$90.8 million in cash and cash equivalents.

Unlike any disease, pain spans numerous medical conditions afflicting literally tens of millions of patients. In Zingo, we have a compelling product that addresses peripheral venous access pain in children and potential expansion to adults. Beyond that, there is significant need for new pain management medicines that provide powerful pain relief without the side effects of today's most potent analgesics. We believe that Adlea can be that product, fulfilling a huge unmet medical need and representing a blockbuster commercial opportunity.

By targeting these unmet needs, we intend to build Anesiva's value for you, our stockholders, and to become the leader in the development and commercialization of novel pharmaceutical products for pain management. We thank you for your continued support.

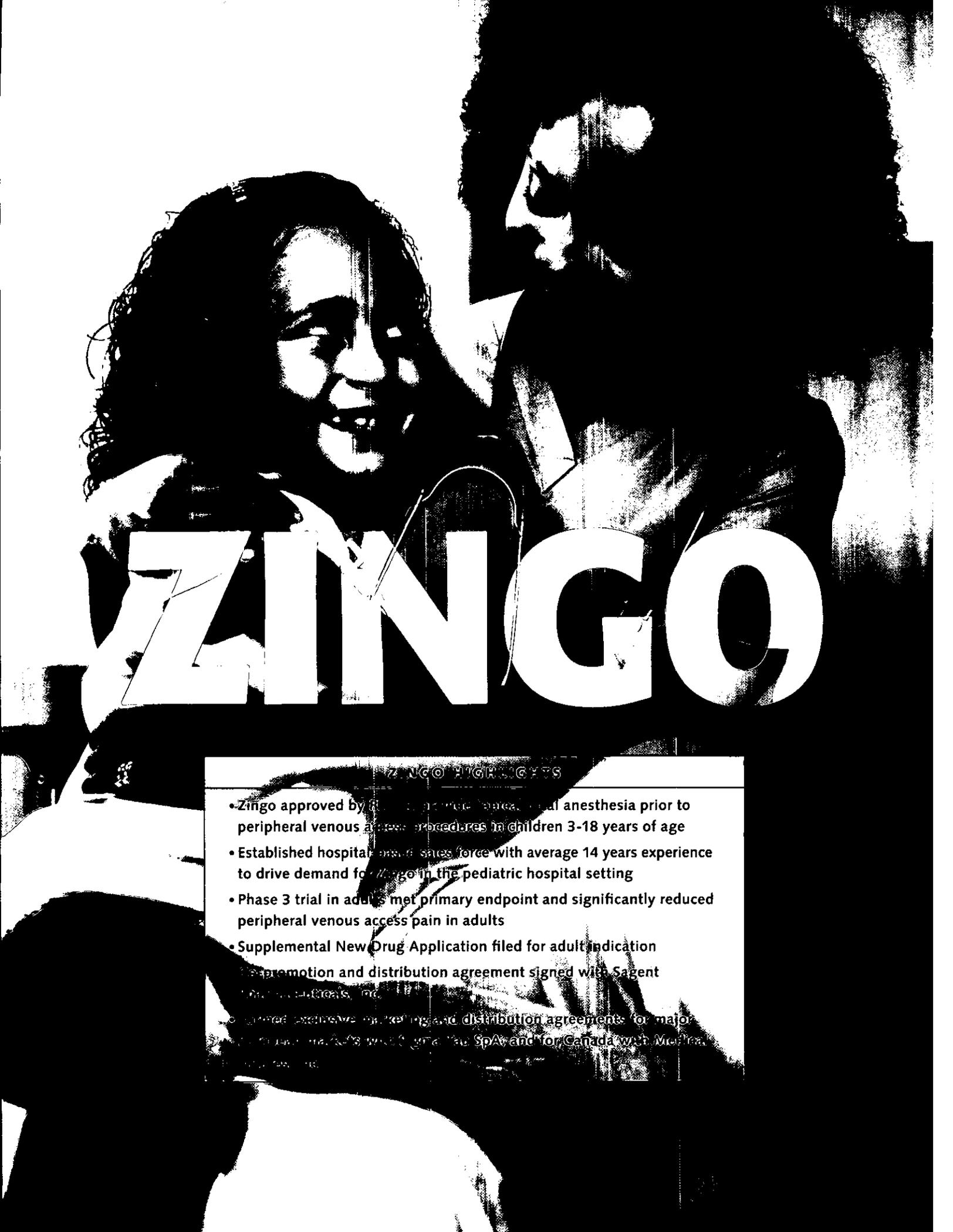
Sincerely,



Rodney A. Ferguson, J.D., Ph.D.  
Chairman of the Board



John P. McLaughlin  
Chief Executive Officer



# ZINGO

## ZINGO HIGHLIGHTS

- Zingo approved by FDA for intravenous local anesthesia prior to peripheral venous access procedures in children 3-18 years of age
- Established hospital and sales force with average 14 years experience to drive demand for Zingo in the pediatric hospital setting
- Phase 3 trial in adults met primary endpoint and significantly reduced peripheral venous access pain in adults
- Supplemental New Drug Application filed for adult indication
- Co-promotion and distribution agreement signed with Sagent Pharmaceuticals, Inc.
- Co-promotion and distribution agreements for major international markets with Cigna Inc. SpA and for Canada with Merck Canada Inc.



## **Zingo (lidocaine hydrochloride monohydrate) powder intradermal injection system: Approved and Preparing to Launch**

### **Approval & Launch Planning**

Zingo is Anesiva's easy-to-administer, single-use, needle-free system that delivers sterile lidocaine powder to provide topical, local anesthesia to reduce the pain associated with peripheral intravenous insertions or blood draws in one to three minutes after administration. In August 2007, the U.S. Food and Drug Administration (FDA) approved Zingo for use in children three to 18 years of age. In clinical trials, the most common adverse reactions were redness, red dots and swelling.

While preparing to launch Zingo in the pediatric population, Anesiva conducted an FDA-requested Phase 3 trial of Zingo for an additional indication in adults. The pivotal trial demonstrated significantly less pain associated with peripheral venous access procedures in patients treated with Zingo compared to placebo. Based on these results and positive data from earlier trials, Anesiva filed a supplemental New Drug Application with the FDA to expand Zingo's label to include adults in March 2008.

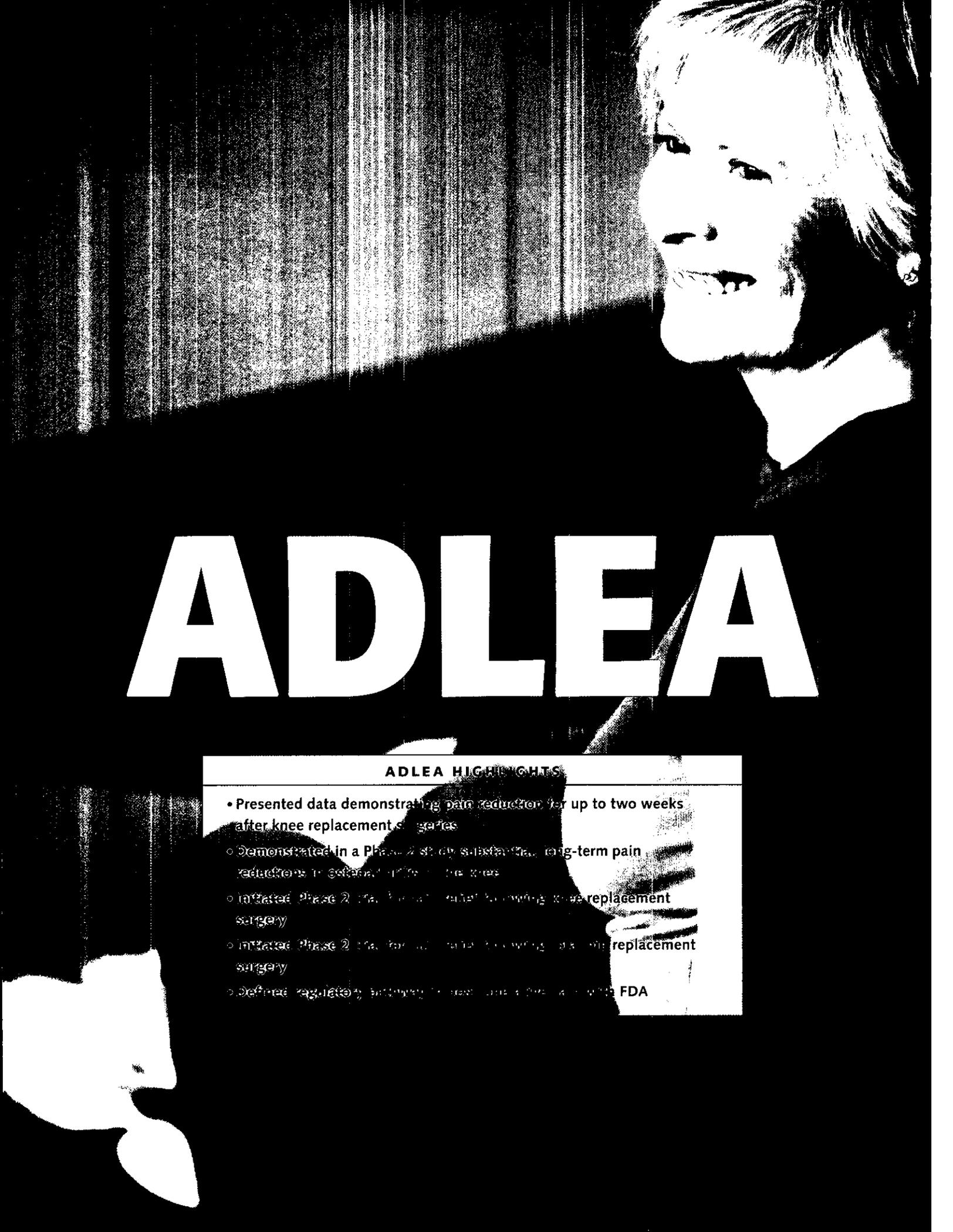
Internationally, Anesiva forged exclusive licensing agreements with Sigma-Tau SpA covering major European markets, and with Medical Futures, Inc. for marketing and distribution of Zingo in Canada. In addition, Anesiva entered into a joint venture

with Wanbang Biopharma in China to supplement U.S. production capacity using U.S.-sourced components.

### **Sales & Marketing**

Selling in hospitals involves two steps: creating product demand and obtaining formulary access. Anesiva's skilled 15-person sales force, under experienced leadership, entered the field in February 2008. Beyond these representatives, Anesiva will co-promote Zingo in the United States under an agreement with Sagent Pharmaceuticals. The Anesiva team is promoting Zingo primarily to healthcare providers, while Sagent's representatives focus on hospital pharmacists and group purchasing organizations, capitalizing on the expertise and strengths of both sales organizations.

Anesiva implemented a number of marketing initiatives aimed to improve peripheral venous access pain management in children: the website [www.ManageIVPain.com](http://www.ManageIVPain.com), an interactive repository of information, guidance and support to parents and healthcare providers, encourages nurses to minimize IV pain for their pediatric patients. A second initiative, RN VOICE (Registered Nurses for Venipuncture Optimization through Increased Comfort and Education), provides its members with resources on improving the management of IV pain in children.



# ADLEA

## ADLEA HIGHLIGHTS

- Presented data demonstrating pain reduction for up to two weeks after knee replacement surgery
- Demonstrated in a Phase 2 study substantial long-term pain reductions in patients with knee pain
- Initiated Phase 2 trial for patients with knee replacement surgery
- Initiated Phase 2 trial for patients with knee replacement surgery
- Defined regulatory pathway for approval with FDA

## **Adlea: Substantial Clinical Progress Across Indications**

### **Efficacy Demonstrated in Trials to Date**

Adlea is a powerful, long-acting, site-specific non-opioid analgesic drug candidate designed to provide pain relief for weeks to months after a single local application. Adlea's unique mechanism of action provides a long-lasting, localized effect and blocks the transmission of moderate to severe pain caused by major surgical procedures and osteoarthritis.

Adlea has demonstrated long-lasting pain reduction in numerous Phase 1 and 2 trials. Treatment with Adlea, which is non-addictive and non-narcotic, may reduce the need for other less safe, systemic pain medications such as opioids and NSAIDs. Reducing use of these standard agents may improve the quality of life for patients recovering from surgeries and those suffering from osteoarthritis.

Adlea can be additive to existing therapies for post-operative pain:

- In a Phase 2 trial in total knee replacement surgeries, patients receiving Adlea had significantly less post-operative pain than patients who received placebo. Both groups received post-surgical analgesia, and there was a trend toward reduced morphine use in the Adlea-treated group as compared to placebo.

- In a Phase 2 trial in bunionectomy surgeries, Adlea treatment resulted in statistically significantly less post-operative pain, at the planned dose to be used in the Phase 3 trial, compared to placebo. Further, a significantly lower proportion of the Adlea-treated patients required post-surgical rescue pain medication relative to placebo.

In the treatment of osteoarthritis pain, Adlea provided sustained reduction in mean pain intensity as compared to baseline over the twelve-week study period in a Phase 2 trial. This lengthy duration of clinical benefit is consistent with Adlea's known mechanism.

### **Regulatory Pathway Defined**

In October 2007, Anesiva announced the planned regulatory pathway for Adlea in post-surgical pain. The company also has initiated Phase 2 trials for post-operative pain associated with total hip replacement and knee replacement surgeries and in pain due to osteoarthritis of the knee.

Anesiva is conducting two Phase 3 trials for Adlea in bunionectomy surgeries and total knee replacement surgeries in 2008 to support a label of pain management following orthopedic surgery.

### **2008 MILESTONES**

- Launch Zingo to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age
- File supplemental New Drug Application for Zingo to expand the label to include adults
- Establish Zingo marketing and distribution agreements in additional territories
- Initiate Phase 3 trial evaluating Adlea in bunionectomy surgeries
- Initiate Phase 3 trial evaluating Adlea in total knee replacement surgeries
- Initiate Phase 2 trial of Adlea in arthroscopic shoulder surgeries
- Report data from Phase 3 trial of Adlea in bunionectomy surgeries
- Report data from Phase 3 trial of Adlea in total knee replacement surgeries

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2007

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

For the transition period from

to

COMMISSION FILE NO. 000-50573

**ANESIVA, INC.**

(Exact Name of Registrant as specified in its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

77-0503399

(IRS Employer  
Identification Number)

650 Gateway Boulevard  
South San Francisco, California 94080  
(650) 624-9600

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT:**

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$0.001 par value per share

Nasdaq Global Market

**SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: NONE**

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant based upon the closing price of the common stock listed on the Nasdaq Global Market on June 29, 2007 was \$91,736,481 based on a closing price of \$6.15 per share, excluding 12,815,278 shares of the Registrant's common stock held by current executive officers, directors and stockholders whose ownership exceeds 5 percent of the common stock outstanding as of such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

The total number of shares outstanding of the Registrant's common stock as of February 29, 2008 was 40,446,031.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement, to be filed with the Commission pursuant to Regulation 14A in connection with the 2008 Annual Meeting of Stockholders, are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

Certain exhibits are incorporated herein by reference into Part IV of this Annual Report on Form 10-K.

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## PART I

### Forward-Looking Statements

This Annual Report on Form 10-K, including particularly the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipates,” “believes,” “continue,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” “will,” or the negative of these terms or other comparable terminology. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K is filed with the Securities and Exchange Commission.

### Item 1. Business

#### Overview

Anesiva, Inc. is a biopharmaceutical company focused on the development and commercialization of novel therapeutic treatments for pain management. Our portfolio of products includes:

- Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, which was approved by the FDA in August 2007 to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. In October 2007, we announced that our Phase 3 clinical trial in adults requested by the Food and Drug Administration (FDA) met its primary endpoint. In March 2008, we submitted to the FDA a supplemental New Drug Application for the use of Zingo in adults.
- Adlea™, a long-acting, site-specific, non-opioid analgesic, is being developed for moderate to severe pain, and has completed multiple Phase 2 trials in post-surgical, musculoskeletal and neuropathic pain. We are pursuing two indications for Adlea—reduction in post-surgical pain following orthopedic surgeries and treatment of osteoarthritis pain—and are executing on a registration-directed plan which involves multiple Phase 2 and Phase 3 studies.

Zingo and Adlea are different drugs, each with its own mechanisms of action. Zingo is comprised of microcrystals of lidocaine delivered into the skin by compressed gas. Zingo employs a proprietary needle-free dispenser. Adlea is a novel non-opioid drug candidate that is a vanilloid receptor 1 agonist, or TRPV1 agonist, based on the compound capsaicin which provides analgesia for between two and three months.

#### Pain Management Market

Pain is a worldwide problem with serious health and economic consequences. The medical effort to treat pain, known as pain management, addresses a large and under-served market. Pain in the hospital is associated with increased length of stay, longer recovery times and poorer patient outcomes, all of which have health care quality and cost implications. Decision Resources estimates that the worldwide prescription market for pain drugs totaled \$27 billion in 2006. In the United States:

- Decision Resources estimates that nearly \$17 billion was spent in 2006 on prescription pain drugs;
- approximately 25 million Americans experience acute pain each year due to injury or surgery, according to the American Pain Society, as published in 2003 by Medtech Insight; and
- approximately 50 million Americans suffer chronic pain, according to the American Pain Society.

According to a 2004 Global Strategic Business Report by Global Industry Analysts, Inc., the prescription pain management market is anticipated to grow at a compounded annual growth rate of nine percent through 2010 due to a number of factors, including:

- a rapidly aging population with an increasing need to address pain-related ailments;
- longer survival times for patients with painful chronic conditions, such as cancer and AIDS;
- patients' increased demand for effective pain relief; and
- increasing recognition of the therapeutic and economic benefits of effective pain management by physicians, other health care providers and payors.

### *Analgesic Drugs*

Drugs that treat pain are referred to as analgesics, and the type of analgesic selected for treatment depends principally upon the severity of the pain. For mild pain, weak analgesics such as acetaminophen or non-steroidal anti-inflammatory drugs, or NSAIDs, such as ibuprofen are used. For moderate pain, NSAIDs, weak opioids such as codeine or short-acting formulations of strong opioids may be used. Severe pain requires strong opioids such as morphine, oxycodone, hydrocodone or fentanyl.

### *Shortcomings of Current Pain Management*

Despite widespread clinical use of drugs for pain, pain management remains less than optimal due to a variety of factors, including:

- *Insufficient efficacy.* Opioids, the current standard of care for severe pain originating from a painful stimulus, or nociceptive pain, reduce pain less than 50 percent in a majority of situations. Pain due to moderate to severe osteoarthritis is also poorly treated, with many patients eventually exhausting available treatment options. Neuropathic pain does not respond to treatment with NSAIDs and responds poorly to treatment with opioids at doses that do not impair the ability of patients to live reasonably active lifestyles.
- *Lack of site specificity.* Most analgesics, including opioids and NSAIDs, are given orally, transdermally or by intravenous infusion and thereby subject the patient to high circulating concentrations of drug, even though most types of pain are experienced in discrete parts of the body. Opioids given by mouth, transdermally or by infusion provide pain relief by acting on nerves all over the body: in the spinal cord, in the brain and at the site of injury. As a consequence, opioids do not provide site-specific pain relief because their action is not targeted specifically to the area of the body that is experiencing pain. Moreover, circulating drugs cause side effects at parts of the body unrelated to the perception of pain. Although there are currently means of delivering site-specific analgesia, such as by injection of short-acting anesthetics into joints such as the ankle or knee, these techniques are reserved to provide relatively short-term anesthesia prior to surgery and are not appropriate for long-term pain relief.
- *Occurrence of side effects.* NSAIDs may cause gastrointestinal ulcers, and between 10,000 and 20,000 patients die each year from gastrointestinal bleeding believed to be related to the use of NSAIDs. Use of opioids is associated with nausea and vomiting in many patients. High-dose opioids cause sedation and may also cause respiratory depression, or a decrease in the ability to breathe spontaneously. Opioids used chronically can cause severe constipation that leads many patients to stop using them, and opioids may sometimes cause severe itching. Drugs used to treat neuropathic pain frequently cause sedation and problems with coordination.
- *Need for frequent dosing.* Many drugs used to treat pain require frequent dosing that is inconvenient, often leading to reduced patient compliance.

- *Slow onset of action.* Local anesthetics that are used prior to procedures involving manipulation of the skin, such as needle-sticks or skin surgery, are typically formulated as patches or creams and have a slow onset of pain relief. This slow onset, as well as poor efficacy, is due to the poor penetration of skin by the anesthetics used in these products.
- *Potential to cause physical dependence.* Opioids, when used chronically, can cause physical dependence. Fear of physical dependence often influences clinicians to prescribe less than adequate doses of opioid analgesics. Similar fears lead many patients to refuse opioid analgesics.

Given doctors' and patients' desire to achieve adequate control of pain, and the significant shortcomings associated with existing treatments, doctors and patients often struggle to find an appropriate balance between pain relief and adverse side effects. With both over- and under-treatment of pain, patients may be suffering unnecessarily, have poor quality of life and have difficulty meeting their social, familial and work-related commitments.

### **Anesiva Product Pipeline**

<u>Project Candidate</u>	<u>Clinical Indications</u>	<u>Development Status</u>	<u>Anesiva Commercialization Rights</u>
Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system	Reduce pain associated with peripheral IV insertions or blood draws	Approved for use in children three to 18 years of age. We filed a sNDA with the FDA for the use of Zingo in adults in March 2008	Co-promotion agreement with Sagent Pharmaceuticals for distribution to U.S. hospitals; Marketing and distribution agreements with Medical Futures in Canada, and Sigma-Tau in six European countries
Adlea™	Post-surgical, musculoskeletal and neuropathic pain	Multiple Phase 2 trials completed and two Phase 2 trials ongoing; additional Phase 2 trials to be initiated for management of pain following orthopedic surgery and management of osteoarthritis pain; two Phase 3 trials for management of pain following orthopedic surgery to start in 2008	100% worldwide

### ***Zingo for the Reduction of Pain Associated with Venipunctures***

The market for pain reduction with venipuncture procedures is an underserved market. Currently, in the largest children's hospitals and academic institutions in the United States, approximately 18 million venipuncture procedures occur each year. Of these 18 million procedures, topical local anesthetics are used in only 2.1 million given that the currently marketed products can take upwards of 60 minutes to offer a benefit. Zingo provides a rapid onset of action, allowing peripheral IV insertions or blood draws to begin one to three minutes after administration. With its fast onset-of-action, additional opportunities exist for Zingo in the adult emergency room setting, hemodialysis and blood donation centers as well as physicians' offices and clinical laboratories. We believe that this market is highly underserved by existing products and believe that the medical community is

interested in reducing the pain associated with venipuncture procedures. In fact, a joint recommendation from the American Academy of Pediatrics and American Pain Society has urged consideration of local anesthetics and strategies to minimize pain and distress for procedures such as blood draws.

Zingo was approved by the FDA in August 2007 to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. Zingo is an easy-to-administer, single-use, needle-free system that utilizes compressed gas to accelerate 0.5 mg sterile lidocaine powder into the epidermis in order to anesthetize nerves. It provides a rapid onset of action, allowing peripheral IV insertions or blood draws to begin one to three minutes after administration, thus offering an important advantage over currently available therapies. In October 2007, we announced positive top-line results from a pivotal Phase 3 trial of Zingo in adult patients, demonstrating less venous procedural pain in those treated with Zingo compared to placebo ( $p=0.003$ ). The trial was requested by the FDA. We submitted a sNDA with the FDA in March 2008 for the use of Zingo in adults. Under the Prescription Drug User Fees Act (PDUFA), this sNDA will be subject to a ten month review.

#### *Clinical trials of Zingo*

Zingo has been evaluated in Phase 1, 2 and 3 clinical trials in more than 2,200 patients. Two Phase 3 trials in the pediatric population were completed in 2005 and demonstrated that Zingo met the primary endpoint in both studies, demonstrating statistically significantly less pain compared with the placebo group. The trials had identical clinical protocols, and the first trial, which included 574 patients, was conducted at six U.S. centers while the second trial, which included 535 patients, was conducted at nine U.S. centers. The pediatric patients, aged three to 18 years, were administered either a placebo or Zingo one to three minutes before either venipuncture or intravenous cannulation. The primary endpoint was pain upon needle insertion utilizing the FACES pain scale. Both studies demonstrated that treatment with Zingo statistically significantly reduced pain ( $p=0.007$  and  $p=0.002$ ) compared with the placebo group. The incidence of adverse events was no higher in the active drug group versus patients who received placebo. The most common adverse reactions to Zingo were redness, red dots and swelling.

In October 2007, we announced positive top-line results from a pivotal Phase 3 trial of Zingo in adult patients. The multi-center, randomized, double-blind study in adult patients enrolled 699 patients in the U.S. Approximately half of the patients received Zingo and the other half received placebo one to three minutes before undergoing medical procedures requiring venipuncture or IV line placement. The primary endpoint was pain upon needle insertion utilizing the VAS pain scale. Demographic characteristics and sites of administration were evenly distributed across treatment groups. The mean pain score in the Zingo-treated patients was significantly lower than in the placebo group ( $p=0.003$ ). The incidence and types of adverse events were similar to that observed in the Phase 3 pediatric trials

#### ***Adlea for the Treatment of Post-surgical, Musculoskeletal or Neuropathic Pain***

Adlea is our product candidate for the treatment of site-specific moderate to severe pain. These types of pain are poorly treated with existing drugs, many of which have well-documented and severe side effects. We are developing Adlea to treat post-surgical pain associated with orthopedic surgeries, including bunionectomy and total knee replacement surgeries, and to treat pain resulting from osteoarthritis. Adlea is delivered directly onto the cut surfaces of muscle, bone and connective tissue during open surgeries and injected into the surgical site during an arthroscopic procedure. For pain resulting from musculoskeletal diseases, such as osteoarthritis and neuropathic pain, it is injected into the site of pain. Prior to use of Adlea in non-surgical settings, patients may receive a pre-treatment with analgesics to ameliorate the transient pain experienced upon injection of Adlea. Such pre-treatment is not required in surgical settings because such patients are typically under a general anesthetic and/or a local nerve block. We will be focusing our near-term development efforts of Adlea in two areas—post-surgical pain and osteoarthritis pain. We initiated two Phase 2 trials of Adlea in post-surgical pain in 2007: one in total knee replacement and one in total hip replacement. We plan to initiate additional Phase 2 trials and two Phase 3 trials for the approval of Adlea for the management of pain following orthopedic surgery in 2008.

Based on ongoing conversations with the FDA, we have developed a registrational program for Adlea consisting of Phase 3 trials in total knee replacement surgeries and bunionectomy surgeries—for a broad product label of management of post-surgical pain associated with orthopedic surgeries. Adlea has already demonstrated statistically significant pain reduction in Phase 2 trials in both of these settings. Both trials are expected to begin in the first half of 2008.

Adlea is a long acting purified capsaicin analgesic. It relieves pain by causing localized desensitization of the TRPV1 receptors on neuronal C fibers. When capsaicin binds to and activates the receptor TRPV1, it desensitizes the pain-sensing endings of the C fibers, thereby preventing the neuron from transmitting pain signals. Clinical and preclinical studies have demonstrated that following Adlea treatment, the C fibers and TRPV1 receptors regenerate over a period of weeks to months. This unique action is the basis for what we believe will be Adlea's ability, if approved, to provide meaningful, long-lasting pain relief following a single administration. Since the product is administered locally at the site of pain and selectively reduces pain in nerve endings, it does not affect other nerve fibers important for other sensory or motor skills. As a consequence, Adlea may be a highly specific pain therapeutic that provides long-lasting analgesia.

Opioid drugs, such as morphine, are currently the most commonly used agents to relieve pain in post-surgical, musculoskeletal and neuropathic pain conditions but are associated with significant side effects including respiratory depression, euphoria, and nausea and vomiting during acute use, and constipation and physical dependence during chronic use. In clinical studies to date, Adlea has not demonstrated similar side effects. Additionally, it has been shown that pain in the hospital is associated with increased length of stay, longer recovery times and poorer patient outcomes. By safely decreasing a patient's level of pain with fewer side effects and associated complications, Adlea may have the potential to reduce length of hospital stay and the need for opioids.

#### *Clinical trials of Adlea*

Adlea has been administered to hundreds of patients to date for the treatment of post-surgical, neuropathic and musculoskeletal pain indications.

#### *Adlea—Post-surgical Pain*

Multiple Phase 1 and Phase 2 clinical trials of Adlea in post-surgical pain indications have been completed. In June 2006, we reported positive, top-line clinical data from a Phase 2 clinical trial in total knee replacement surgeries showing that Adlea demonstrated pain reduction at all pre-specified time intervals in the study, including statistically significant pain relief at day one ( $p=0.0273$ ) and at day 14 ( $p=0.0071$ ). The difference in average daily pain scores between the Adlea-treated group ( $n=25$ ) and the placebo group ( $n=25$ ) on day one was statistically significant and showed a relative difference in pain on first ambulation of 24 percent. On a numerical rating scale of zero to 10, the average pain score for the treated group was 5.4 compared with the placebo group's average of 7.1. It is noteworthy that this difference was detected despite all patients being on concomitant morphine. On day 14, the patients' "worst pain in the previous 24-hour period" using the Brief Pain Inventory form showed a relative difference of 34 percent with the average pain scores being 3.9 and 5.9 for the treated group and placebo group, respectively. The preliminary data showed that Adlea was safe and well tolerated.

Two Phase 2 trials evaluating patients undergoing bunionectomy surgery were completed. The first trial, which treated 40 patients, demonstrated a statistically significant reduction in the use of rescue medication during the first 72 hours following surgery in a subset of patients receiving Adlea with adequate pretreatment as compared to patients receiving placebo. The second trial, which treated 182 patients, demonstrated a statistically significant reduction in the magnitude of pain suffered during the first 32 hours following surgery by those subjects who received the recommended dose of Adlea. In March 2006, a Phase 2, 41-patient clinical trial evaluating Adlea in hernia repair pain was completed. While Adlea was well tolerated at all time points during the study, there was no significant difference in pain score in the drug versus control arm at the pre-specified

time point of pain measured during the seven days following surgery. Although it was not the primary endpoint, Adlea did reduce pain over the three days following surgery in a statistically significant manner. Additionally, we reported in June 2006 that in a Phase 2 trial of Adlea in 44 patients undergoing cholecystectomy (gall bladder removal) surgeries, the trial did not show a difference in pain scores between those receiving Adlea and those receiving placebo, potentially because the extent of contact between the drug and the relevant tissues in the cholecystectomy surgeries may not have been maintained at a level sufficient to provide therapeutic benefit.

#### *Adlea—Musculoskeletal Pain*

Multiple trials evaluating Adlea in musculoskeletal pain indications have been conducted, including several studies in osteoarthritis of the knee. A Phase 1 and Phase 2 trial, which treated 28 end-stage osteoarthritis patients across the two trials, demonstrated that Adlea was shown to be safe and well-tolerated. In the Phase 2 trial, which was designed to assess efficacy as well as safety, there was a statistically significant reduction in pain in the Adlea-treated group compared with patients who received placebo. Additionally, at all time points, pain was found to have been reduced by approximately 50 to 60 percent in the patients treated with Adlea, while pain was not meaningfully reduced in the placebo-treated group. A 45-patient, Phase 2 trial evaluating Adlea for the treatment of tendonitis of the elbow met its primary endpoint and demonstrated a statistically significant reduction in pain at four weeks in the Adlea-treated group compared to the group who received placebo ( $p=0.0256$ ). For patients treated with Adlea, a statistically significant improvement was maintained at least eight weeks after treatment compared to placebo, and the trend for Adlea patients to have lower pain scores was maintained from two to 12 weeks (the last time point in the efficacy follow-up). In a 55 patient Phase 2 open label trial in patients with moderate and severe osteoarthritis of the knee, various pre-treatment regimens and a stepped dose regimen were explored. There was a statistically significant reduction in pain from baseline using various measures lasting eight weeks after a single injection ( $p<0.001$ ).

#### *Adlea—Neuropathic Pain*

A Phase 2 trial evaluating Adlea in the neuropathic pain indication of intermetatarsal (Morton's) neuroma was completed in late 2005. In the 58-patient randomized, double-blind, placebo-controlled clinical trial, conducted at two study centers in the United States, the group consisting of 30 subjects who received Adlea had statistically significant decreases in their foot pain four weeks after the single administration of study drug. The mean baseline pain score (0-10 Numeric Rating Scale) was 5.7 for subjects in each treatment group. Pain scores were reduced at four weeks following the single administration of Adlea, with a mean pain score of 2.1 (63 percent reduction in pain) compared to 3.5 (38 percent reduction in pain) in subjects treated with placebo ( $p=0.0188$ ). Additionally, Adlea was well tolerated and did not demonstrate any significant safety issues. Morton's neuroma is a painful neuropathic condition of the foot that typically occurs as a result of wearing high narrow shoes, running, or spending considerable time standing each day.

#### **Additional Product Candidates**

1207, the third clinical stage candidate in our pain therapeutics pipeline, was being evaluated as a topical anesthetic for neuropathic patients. The product candidate was shown to be safe and well tolerated in a Phase 1 clinical trial conducted in 2006, but no clear anesthetic effect was demonstrated, so we discontinued clinical development of 1207 in early 2007.

#### **Strategy**

Our objective is to create a fully-integrated biopharmaceutical company focused on the development and commercialization of products for the treatment of pain management. Key elements of our strategy include:

- *Prepare for Commercial Introduction of Zingo.* Deploy our sales force to prepare for the launch of Zingo in patients aged 3-18 years of age in the second quarter of 2008. Filed for product approval in adult population in March 2008.
- *Advance Adlea into Phase 3 Trials.* Conduct two Phase 3 trials in total knee replacement and bunionectomy surgeries during 2008.

- *Be Opportunistic About Partnering our Existing Products and About Expanding Our Pain Management Franchise.* Evaluate partnership opportunities for Zingo and Adlea that would provide maximum exposure of these products in the marketplace. Seek to in-license product candidates that would enhance our product pipeline of pain management products.

## **Sales and Marketing**

Joining the existing marketing team in preparation for the U.S. commercial introduction of Zingo for pain reduction associated with venipunctures in children ages three to 18, we established a sales organization. This group is initially focused on the pediatric hospital setting where there are approximately 18 million venipuncture procedures annually. We have trained and deployed our hospital sales force of 15 sales regional account managers whose focus is to create demand for Zingo by educating nurses and physicians on the importance of treating IV pain and on the features and uses of Zingo for their pediatric patients

In October 2007, we signed a three year co-promotion and distribution agreement with Sagent Pharmaceuticals, Inc. Under the agreement, Sagent will join with us to co-promote Zingo within hospitals as well as facilitate contract negotiations with hospitals and group purchasing organizations in the U.S. Complementary to our sales force's focus on nurses and physicians, Sagent's sales force will focus their selling efforts toward hospital pharmacists. In addition, Sagent will manage Zingo warehousing and distribution services. The terms of the agreement provide for Sagent to earn a royalty based on net sales of Zingo and for us to reimburse Sagent for certain direct expenses, such as distribution and management of orders. We may designate additional marketing partners to address non-hospital affiliated markets in the U.S.

In December 2007, we announced an agreement granting an exclusive license to Medical Futures Inc. for the marketing and distribution of Zingo in Canada. Under the terms of the agreement, Medical Futures will be responsible for all regulatory filings, marketing, distribution and selling in Canada. In February 2008, we announced an agreement granting an exclusive license to Sigma-Tau for the marketing and distribution of Zingo in Belgium, France, Germany, Italy, Luxembourg and the Netherlands. Under the terms of the agreement, Sigma-Tau will oversee all necessary regulatory filings and will be responsible for all marketing and sales of Zingo in their territory. We are evaluating additional marketing and distribution agreements for other European countries and other territories.

With its fast onset of action, additional potential future opportunities for Zingo include adult hospital setting, hemodialysis and blood donation centers as well as physicians' offices and clinical laboratories.

## **Manufacturing**

We currently have limited manufacturing facilities. We have acquired manufacturing equipment and certain leasehold modifications that have been installed at our contract manufacturer facilities in the U.S. and have entered into arrangements with various third parties for the manufacture of our clinical and commercial supplies. These supplies and their manufacturing facilities as well as our own facility must comply with regulations and current good laboratory practices or cGLPs, and current good manufacturing practices or cGMPs, as applicable and enforced by the FDA. We plan to continue to outsource substantially all manufacturing for our clinical and commercial supplies of Zingo and Adlea.

There are a small number of suppliers of the materials which are necessary to manufacture Zingo. The cylinder of compressed helium gas is a key component in the dispenser for Zingo. We acquire the cylinders for Zingo from PowderMed Limited, a wholly-owned subsidiary of Pfizer, Inc., under a long-term supply agreement. PowderMed Limited is currently our sole supplier and source of such cylinders, which are manufactured for it by Linde AG, and to date we have not identified an alternative source. If we are required to seek an alternative source for the cylinders, we might not be successful in establishing an alternative commercial arrangement with a supplier, or, if we were successful in finding an alternate supplier, it could be on terms which are less favorable

than our current supply agreement with PowderMed Limited. Other than for the cylinder used in Zingo, we believe that there are alternate manufacturers available to produce our clinical and commercial supplies of Zingo's components.

In October 2007, we entered a joint venture with Wanbang Biopharma, a Fosun company, of XuZhou, China to establish additional manufacturing capacity for worldwide supply utilizing materials sourced in the U.S. The operation will provide a second source for Zingo commercial supply, assist with ongoing efforts to reduce manufacturing costs, and provide additional manufacturing capacity. Anesiva owns 49 percent of the joint venture, which is named Wanbang Anesiva (Jiangsu) Pharmaceuticals Ltd. The production area will be located at an existing Wanbang facility in the city of XuZhou in Jiangsu province. Following completion of the assembly facility in XuZhou, the joint venture will seek FDA certification of the facility.

We are currently using contract manufacturers to supply Adlea for clinical trials. There are multiple sources for the active ingredient, capsaicin, which is extracted from plant material and purified. We expect that we will use third parties to manufacture clinical and commercial supplies of Adlea.

### **License, Marketing and Distribution Agreements**

#### ***License Agreement with James N. Campbell, M.D., Richard A. Meyer, M.S. and Marco Pappagallo, M.D.***

In August 2001, we entered into an agreement with James N. Campbell, M.D., Richard A. Meyer, M.S. and Marco Pappagallo, M.D. to acquire the exclusive, worldwide license to U.S. Patent Application No. 09/041294 (U.S. Patent No. 5,962,532) and all applications and products relating thereto directed to methods and kits for relieving pain using capsaicin as an anesthetic. The technology licensed under the agreement relates to the steps of administering capsaicin for pain reduction that we use in our product Adlea. This license excludes topical application to the skin of capsaicin and analogues. Upon execution of the agreement, the licensors were paid an aggregate up-front license fee of approximately \$42,000, granted options for an aggregate of 21,667 shares of common stock of AlgoRx Pharmaceuticals, Inc. and reimbursed for expenses associated with filing, prosecution and maintenance of the patent. Upon our merger with AlgoRx, these stock options were terminated. We are obligated to pay Drs. Campbell and Pappagallo and Mr. Meyer royalties on any future sales of Adlea by us and any of our sublicensees. We are also obligated to pay up to \$775,000 in milestone payments under the agreement, of which, as of December 31, 2007, we have paid an aggregate of \$200,000. Of the remaining milestone payments, we are obligated to pay \$25,000 upon the grant of a Japanese patent using the licensed technology, \$200,000 upon the first administration of licensed technology in a Phase 3 clinical trial and \$350,000 upon approval of the licensed technology for commercial use by the FDA. The license terminates on March 12, 2018, the date of expiration of the patent (U.S. Patent No. 5,962,532), or earlier upon the date of the invalidation of the patent. Our rights under this agreement can be terminated on 10 days' written notice if we fail to fulfill any material obligation under the agreement and the failure is not cured by us within 180 days of receiving notice of such failure. We can terminate the agreement upon 30 days' prior notice for any reason or upon 10 days prior notice for the failure of any counterparty to fulfill a material obligation not cured within 90 days of our giving notice of the failure. The license is subject to a license granted by Drs. Campbell and Pappagallo and Mr. Meyer to Johns Hopkins University for non-profit purposes. The license is subject to a sublicense to the inventors for research and development, with no right to commercialization.

#### ***License Agreement with Marco Pappagallo, M.D.***

In August 2001, we entered into a non-exclusive, worldwide license agreement with Marco Pappagallo, M.D. for U.S. Provisional Patent Application No. 60/006,385 and U.S. Utility Patent Application No. 08/746,207 (U.S. Patent No. 6,248,788) directed to methods of treating neuropathic pain using capsaicin anesthetic, and all applications and patents relating thereto. The licensed technology relates to the use of capsaicin for pain relief. The primary patent underlying the license expires on November 6, 2016. This license agreement makes reference to the August 2001 license agreement between us and Drs. Campbell and Pappagallo and Mr. Meyer and provides that if Dr. Pappagallo develops or has any right to any technology under U.S. Patent

No. 6,248,788 relating to an injectable product or service using capsaicin and its analogues for pain relief, the technology will be licensed to us pursuant to the terms of the August 2001 license agreement with Drs. Campbell and Pappagallo and Mr. Meyer. We are also obligated to pay up to \$222,000 in milestone payments, and we have made no milestone payments to date. Of the \$222,000 in milestone payments, \$40,000 is payable upon the first administration to a subject using licensed technology in a Phase 1 clinical trial, \$66,000 is payable upon the first administration to a subject using licensed technology in a Phase 3 clinical trial and \$116,000 is payable upon FDA approval of the first product using licensed technology. With respect to the licensed technology, we are obligated to pay Dr. Pappagallo royalties on any future sales by us or our sublicensees of transdermal or topical products or services developed from the licensed technology. If at any time Dr. Pappagallo becomes the exclusive owner of the licensed technology, the royalty payments that we are obligated to pay will increase and we will be obligated to make milestone payments of up to \$666,000. Our rights under the agreement can be terminated on 10 days' written notice if we fail to fulfill any material obligation under the agreement and the failure is not cured by us within 180 days of receiving notice of such failure. We can terminate the agreement upon 30 days' prior notice for any reason or upon 10 days' prior notice for the failure of any counterparty to fulfill a material obligation not cured within 90 days of our giving notice of the failure. The license is subject to a sublicense to the inventors for research and development, with no right to commercialization.

#### ***License with PowderMed Limited***

In March 2002, we acquired from then PowderJect Research Limited and now PowderMed Limited, a wholly-owned subsidiary of Pfizer, Inc., a license to intellectual property consisting of over 150 patents and applications relating to the methods and apparatus for the delivery of powder forms of medications. The technology licensed under this agreement with PowderJect includes the technology underlying its product Zingo. The license is exclusive worldwide with respect to products delivered by powder injection into the space between cells under the skin, except for certain immune products and certain products defined as "cytokine drugs" and except for products to which PowderJect retains the exclusive right for delivery in dental procedures to the extracellular space within the oral cavity. With respect to Zingo, we are required to pay royalties to PowderMed Limited on any future direct sales and any future sales effected by any sublicense. For products other than Zingo resulting from the licensed technology, we are also obligated to pay PowderMed Limited royalties on any future direct sales. We must also pay royalties on licensing fees, milestone payments, royalty payments, transfer price and other consideration that we receive from any sublicensees, if any.

#### ***Collaboration, Development and License Agreement with Bridge Pharma, Inc.***

In October 2004, we entered into an agreement with Bridge Pharma, Inc. under which we acquired the exclusive worldwide license to proprietary technology relating to certain analgesic and local anesthetic pharmaceutical agents and compounds. The licensed technology relates to 1207. In January 2007, we announced that we halted the clinical development of this product based on results from a Phase 1 clinical trial showing no efficacy. The agreement also grants us the right to research, develop, sell, import or otherwise commercialize products based on such compounds, provided such products are an analgesic and/or local anesthetic for human or animals in any route of administration, including without limitation, dermal, mucosal, dental, ophthalmic or injection. Upon execution of the agreement, Bridge Pharma, Inc. was paid an up-front license fee consisting of a cash payment of \$1 million and the issuance of 160,000 shares of AlgoRx Pharmaceuticals, Inc. common stock. We paid Bridge Pharma \$200,000 for the commencement of Phase 1 trials in October 2006. We terminated our license in September 2007.

#### ***Co-Promotion and Distribution Agreement with Sagent Pharmaceuticals, Inc.***

In October 2007, we entered into a three year co-promotion and distribution agreement with Sagent relating to Zingo. Under the agreement, Sagent will co-promote Zingo in the U.S. for a period of three years. Complementary to our sales force's focus on nurses and physicians, Sagent's sales force will focus their selling

efforts toward hospital pharmacists. We paid Sagent a set up fee and will pay royalties on net sales of Zingo to hospitals and related markets during an agreed-upon time period. In addition, we will reimburse Sagent for certain direct expenses, such as distribution and warehousing costs. Under the agreement, we may designate additional marketing partners to address non-hospital markets

#### ***Distribution and Marketing Agreements with Sigma-Tau***

In February 2008, we entered into an exclusive marketing and distribution agreement with Sigma-Tau for Zingo in six European countries: Belgium, France, Germany, Italy, Luxembourg and the Netherlands. Under the terms of the agreement, Sigma-Tau will oversee all necessary regulatory filings, and will be responsible for all marketing and sales of Zingo in their territory. The agreement includes an upfront payment to us and an agreed-upon transfer price, as well as milestone payments

#### ***Marketing and Distribution Agreement with Medical Futures***

In December 2007, we entered into an exclusive agreement with Medical Futures Inc. for the marketing and distribution of Zingo in Canada. The agreement includes an up-front payment and agreed-upon transfer price. Medical Futures will be responsible for all of the costs associated with regulatory, distribution, marketing and selling activities.

#### ***Specific-Use License of Needle-Free Drug Delivery Technology with Particle Therapeutics***

In August 2007, we entered into an agreement with Particle Therapeutics Limited under which we granted Particle Therapeutics a specific-use license to incorporate our drug delivery technology into its needle-free, intradermal delivery system for glucagon, a hormone commonly used for the treatment of hypoglycemia associated with Type 1 and Type 2 diabetes. Under the terms of the license agreement, we received an up-front payment, and are entitled to milestone payments for certain key clinical and regulatory achievements, royalties on future sales, as well as royalties on revenues from any future sub-licensing of the technology by Particle Therapeutics.

#### **Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2007, we own or license approximately 630 United States and foreign patents and pending patent applications. Our patents expire between 2013 and 2020.

Specifically, we currently own or license approximately 70 patents and patent applications related to our capsaicin technology, compounds and their application in pharmaceutical development or their use as pharmaceuticals. We believe these issued patents and pending applications, if and when issued, will provide us with intellectual property protection in the methods of purification, manufacture, medical use and formulation of capsaicin. This technology relates to our Adlea product. We also license over 450 patents and patent applications relating to the methods and apparatus for delivering powder forms of medications. This portfolio includes the technology underlying our Zingo product.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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. In fact, one of our issued European patents covering capsaicin for injection has been challenged by Grunenthal, a German pharmaceutical company, in the European Patent Court. In response to this challenge, we submitted proposed modifications to the patent which the patent court approved and published in November 2004. The amended patent can be objected to by Grunenthal or any other third party within two months following publication of the amended patent by the court. The two month period for filing an objection has expired, and we are not aware of any objections filed against the amended patent. If any future challenge by Grunenthal or any other party is ultimately successful in invalidating the patent, the ability of third parties to market competing technologies to Adlea in Europe could be enhanced.

We rely on trade secrets to protect our technology in addition to patents, especially where patent protection is believed not to be appropriate or obtainable. However, trade secrets are difficult to protect. We attempt to protect our proprietary technology, in part, with appropriate agreements with our employees, consultants and collaborators. There can be no assurance that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our commercial success will depend in part on not infringing upon the proprietary rights of third parties and on not breaching the technology licenses pursuant to which we have obtained certain of our proprietary rights, but we may be infringing on third party rights. It is uncertain whether the issuance of any third party patent would require us to alter our products or processes, obtain licenses or cease certain activities. Our breach of our license agreements or failure to obtain a license to technology that we may require to discover, develop or commercialize our future products may have a material adverse impact on us. One or more third party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention.

## **Competition**

The development and commercialization of new drugs is highly competitive. We will face competition with respect to Zingo, Adlea and any products we may develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Zingo will face significant competition in the commercial marketplace. Two leading products for local anesthesia prior to venipuncture procedures were L.M.X.4<sup>®</sup>, a cream-based product from Ferndale Labs, and EMLA<sup>®</sup>, a cream-based product sold by APP Pharmaceuticals. A third product, Synera<sup>™</sup>, was launched by ZARS/Endo Pharmaceuticals Inc. during 2006. EMLA<sup>®</sup> has historically been the market leader, and several generic versions of EMLA<sup>®</sup> that are manufactured by Fougera, Atrix, Geneva, and Hi-Tech Pharmaceuticals

were approved by the FDA. These products already have established distribution channels and are well known to physicians and hospitals. There are additional products including Numby Stuff® (Iomed) and LidoSite® (Vyteris) with more rapid onset than the cream-based products above that may also compete with Zingo.

The key competitive factors affecting the success of Zingo are likely to be the efficacy, safety profile, price and adoption by the market of Zingo as well as existing therapies for the prevention of pain associated with venipunctures. The commercial success of Zingo will depend upon the product label and experience with the product in the commercial marketplace. We have not yet determined the price for Zingo and do not expect to do so before commercial launch.

Adlea, if approved and commercialized, will face significant competition. For post-surgical pain, morphine administered by infusion pump is a common treatment method. Several other oral, injectable and patch opioids are also used, including Vicodin® (Abbott Labs), OxyContin® (Purdue Pharma), and Duragesic® (Johnson & Johnson). For later-stage osteoarthritis, glucocorticosteroids and hyaluronic acid products, including Synvisc® (Genzyme), a market leader in 2007, are injected locally and several oral opioids, most prominently OxyContin® (Purdue Pharma) and Duragesic® (Johnson & Johnson) are used. For localized neuropathic pain, Neurontin® (Pfizer) and tricyclic antidepressants are used to treat neuropathic pain. For the treatment of tendonitis, glucocorticosteroids are used. TRPV1, which is involved in the transmission of pain signals to the brain and which is affected by Adlea, has become a popular target for the pharmaceutical industry. TRPV1 antagonists that may also compete with Adlea are being developed by several companies, including Lilly, GlaxoSmithKline, Merck-Neurogen, Pfizer, Amgen, Purdue Pharma and Abbott. Some of these TRPV1 antagonists are in the clinic and others may advance to clinical evaluation.

## **Government Regulation**

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the safety, efficacy, research, development, testing, manufacture, storage, record-keeping, labeling, promotion, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing.

### ***United States Government Regulation***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

Our products are considered by the FDA to be drugs. The drugs are subject to FDA review and approval or clearance. If the FDA denies approval or clearance of the drugs, our ability to market our products could be significantly delayed or precluded.

The steps required before a drug may be marketed in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under FDA's good laboratory practices regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;

- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP;
- FDA review and approval of the NDA before any commercial marketing, sale or shipment of the product.

Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical tests may begin, in order to ensure that human research subjects will not be exposed to unreasonable health risks. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA has placed the IND on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing the trial to commence on the terms originally specified in the IND.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND before the clinical trial may begin. Each trial must be reviewed and approved by an independent Institutional Review Board, or IRB, before it can begin and the trial is subject to IRB oversight. The FDA, the IRB or we may discontinue a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice (GCP) requirements and the requirements for informed consent.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness.

Phase 2 trials usually involve controlled trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including extensive manufacturing information and information on the composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more specified indications. An NDA may also be submitted in the format of an electronic Common Technical Document, or eCTD, which under ICH guidelines, is acceptable to the FDA and many foreign regulatory authorities. The FDA reviews an NDA or eCTD to determine, among other things, whether a product is safe and effective for its intended use.

Before approving an application, the FDA will inspect the facility or the facilities at which the product is manufactured, and will not approve the product unless cGMP compliance is satisfactory. The FDA will also inspect the clinical sites at which the trials were conducted to assess their compliance, and will not approve the product unless compliance with Good Clinical Practice requirements is satisfactory. If the FDA determines the application demonstrates that the product is safe and effective for the proposed indication and that the manufacturing process and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and may deny the application, limit the indication for which the drug is approved or require additional post-approval testing in other requirements.

The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

If and when regulatory approval of a product is obtained, we will be required to comply with a number of post-approval requirements. We also must comply with other regulatory requirements, including cGMP regulations and adverse event reporting. Holders of an approved NDA are required to report certain adverse reactions and production problems, if any, to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional activities for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We use, and will continue to use at least in the near term, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, although within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union state. The time required to obtain regulatory approval outside the United States may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

## Third Party Reimbursement and Pricing

### *General*

In the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. In determining payment rates, third party payors are increasingly scrutinizing the prices charged for medical products and services. Our products may not be reimbursed by these third party payors at rates sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments for pharmaceuticals by governmental payors. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### Financial Information by Business Segment and Geographic Data

We operate in one segment, the discovery, development and commercialization of pain therapeutics. During 2002 and 2003 we had revenue in the United States, which was derived from the licensing of technology acquired as part of the PowderJect acquisition that we did not intend to develop ourselves. During 2004 and 2005 we had no revenue, and during 2006 and 2007 we had revenue in the United States that was derived from the out-licensing of technology. All of our long-lived assets are located in the United States.

### Employees

As of December 31, 2007, we had 100 full time employees, 18 of whom hold Ph.D., M.D. or comparable degrees and 20 of whom hold other advanced degrees. Our employees are not represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

### Executive Officers and Key Employees

Our executive officers and other key employees and their respective ages as of March 7, 2008 are:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Executive Officers:</b>		
John P. McLaughlin .....	56	Chief Executive Officer and Director
Patrick A. Broderick .....	49	Vice President, General Counsel and Corporate Secretary
Nancy E. Donahue .....	41	Senior Vice President, Marketing
John X. Regan .....	52	Senior Vice President, Operations
Jean-Frédéric Viret, Ph.D. ....	42	Vice President and Chief Financial Officer
<b>Key Employees:</b>		
James R. Carr, Pharm.D. ....	45	Vice President, Marketing
Susan M. Kramer, Dr.P.H. ....	58	Vice President, Preclinical Development
Samantha R. Miller .....	42	Vice President, Business Development
Melissa Morandi .....	43	Vice President, Quality Assurance
Yvonne Richardson .....	53	Vice President, Manufacturing

## Executive Officers

*John P. McLaughlin* has been our chief executive officer and a member of our board of directors since January 2000. From December 1997 to September 1999, Mr. McLaughlin was president of Tularik Inc., a biopharmaceutical company. From September 1987 to December 1997, Mr. McLaughlin held a number of senior management positions at Genentech, Inc., a biopharmaceutical company, including executive vice president. From January 1985 to September 1987, Mr. McLaughlin was a partner at a Washington, D.C. law firm specializing in food and drug law. Mr. McLaughlin served as counsel to various subcommittees in the United States House of Representatives, where he drafted numerous measures that became FDA laws. Mr. McLaughlin is a co-founder and former chairman of the board of directors of Eyetech Pharmaceuticals, Inc., a biopharmaceutical company, and is formerly a director of IDEC Pharmaceuticals. He is currently a director of Seattle Genetics, a public biopharmaceutical company, and Peak Surgical, a private medical device company. He received a B.A. in Government from the University of Notre Dame and a J.D. from the Catholic University of America.

*Patrick A. Broderick* has been our vice president, general counsel and corporate secretary since July 2004. From 2003 to 2004, Mr. Broderick was vice president, secretary and general counsel of DaVita Inc., the largest independent provider of dialysis services in the United States. From 1999 to 2002, he served as general counsel of COR Therapeutics, Inc. From 1993 to 1998, Mr. Broderick served in a variety of in-house legal positions for McKesson Corporation, a drug wholesaler, including counsel to PCS Health Systems and Healthcare Delivery Systems, Inc. Prior to joining McKesson, he served as an attorney at the law firms of Morrison & Foerster and McCutchen, Doyle, Brown and Enersen. He received a B.A., summa cum laude, from Harvard College where he was elected to Phi Beta Kappa. Mr. Broderick received a J.D. from Yale Law School where he was an editor of the Yale Law Journal.

*Nancy Donahue*, our senior vice president of marketing, joined Anesiva in January 2004. From May 1989 to March 2004, Ms. Donahue worked with GlaxoSmithKline, working in several product marketing positions, as well as strategic alliances and sales. Most recently, she served as executive director of Avandia franchise marketing, which at the time included one pre-launch and two marketed products within the diabetes area. She led the marketing team responsible for developing and implementing the strategic business plan, which resulted in a successful product introduction and franchise sales growth. Previously, she served as product director and senior product manager for Coreg, a treatment for hypertension, recent heart attack and heart failure. Her work on the product included leading the brand team, developing and implementing a strategic business plan and chairing a joint marketing committee with co-marketer, Roche. Her efforts on Coreg helped achieve 56% and 42% sales growth during two recent years leading the product team. Prior to that, Ms. Donahue served as associate product manager for Relafen, an antiarthritic, for which she attained record sales with a mature brand in a flat market. Also with GSK, she held positions in strategic alliances and new product development, hospital products and sales. She holds a B.S. in marketing from Saint Joseph's University, located in Philadelphia, Pennsylvania.

*John X. Regan*, our senior vice president of operations, has been with Anesiva since December 2002. Mr. Regan joined Anesiva from Genentech, where he served most recently as senior director of manufacturing collaborations. During a 19-year career with Genentech, from January 1983 to December 2002, Mr. Regan gained experience with virtually every aspect of manufacturing operations, including: managing numerous facilities involved in all stages of the drug manufacturing process; designing and validating new facilities and expansion of existing facilities; serving as the manufacturing representative during Food and Drug Administration inspections and review; identifying, negotiating contracts with, and overseeing operations at drug and device contract manufacturers; and managing the manufacture of Genentech's marketed products. Prior to Genentech, Mr. Regan was with SmithKline Diagnostics, where he was responsible for the trial formulation, testing and manufacture of medical diagnostics. He holds a B.S. degree from the University of Massachusetts. Mr. Regan is on the editorial advisory board of Contract Pharma Magazine. He is also a member of the Parenteral Drug Association (PDA), International Society of Pharmaceutical Engineering (ISPE) and American Association of Pharmaceutical Scientists.

*Jean-Frédéric Viret, Ph.D.* was appointed vice president and chief financial officer in March 2008. He joined Anesiva in 2002 and was promoted to vice president, finance in 2006. Prior to Anesiva, Dr. Viret was associate director of finance at Tularik Inc. (acquired by Amgen) from March 2000 to November 2002. He served as a senior associate with PricewaterhouseCoopers from 1997 to 2000. Dr. Viret holds an M.B.A. from the Johnson School at Cornell University, and a Ph.D. in molecular biology from the Université Louis Pasteur. He completed a postdoctoral fellowship in molecular biology at the Massachusetts Institute of Technology and was a visiting fellow in molecular biology at Harvard University. Dr. Viret is also a certified public accountant.

### **Key Employees**

*James R. Carr, Pharm.D.*, our vice president of marketing, joined Anesiva in August of 2004. From October 1996 to August 2004, Mr. Carr worked at GlaxoSmithKline, working initially as a regional medical scientist before transitioning into product marketing. Most recently, he led the Lifecycle efforts for the product, Avandia and was also responsible for all medical education initiatives for the brand. Previously, Mr. Carr worked for several years on the cardiovascular drug, Coreg, where he launched the post-myocardial infarction indication. In addition, he led the Lifecycle efforts for the brand, including the development of Coreg CR, a once daily formulation. Between product marketing roles, Mr. Carr worked in New Product Planning for cardiovascular drug development. In this capacity, he spent the majority of his time evaluating new molecule licensing opportunities for the company, as well as developing commercial plans for several in-house assets. Prior to joining GlaxoSmithKline, Mr. Carr worked at Millard Fillmore Hospital in Buffalo, New York and had a joint appointment with the State University of New York at Buffalo School of Pharmacy. Mr. Carr holds a Doctor of Pharmacy degree (Pharm.D.) from the University of Minnesota, Minneapolis.

*Susan Kramer, Dr.P.H.* joined Anesiva in April 2006 as vice president, preclinical development. Dr. Kramer joined Anesiva from BAS Medical, where she was a co-founder and served as vice president of research and development from July 2003 to March 2006. She was instrumental in the initiation of the company's preclinical and clinical programs and participated in the raising of Series A and B funds. Prior to BAS Medical, Dr. Kramer worked at Genentech for 18 years in a number of roles of increasing management responsibility, including director of product development, senior director of bioanalytical technology and ultimately as senior director of development sciences operations and strategic planning. She served as project team leader for products Actimmune® and Raptiva®. She led numerous pharmacology subteams and served on several key committees, including the Product Development Committee. Prior to Genentech, Dr. Kramer served as the director of Medical Laboratories in Montes Claros, Minas Gerais, Brazil as a Peace Corps Volunteer, followed by a stint as head of the clinical virology laboratory at the UCSF Medical Center at the onset of the AIDS epidemic. Dr. Kramer holds Dr.P.H. and M.P.H. degrees in Biomedical Sciences from the University of California, Berkeley.

*Samantha R. Miller* joined Anesiva in August 2006 as vice president, business development. Prior to joining Anesiva, Ms. Miller was with Theravance, Inc. since April 2002 where she most recently served as senior director of business development and as the leader of the gastrointestinal program. At Theravance, she was instrumental in the negotiation and execution of four major alliances as well as several manufacturing, in-licensing and other collaborations. From July 1999 to April 2002, she served as director of business development at Nektar (formerly Inhale), and prior to that, she served as a senior director of business development at Scios Pharmaceuticals and as manager of business development at Onyx Pharmaceuticals, as well as associate product manager at Procter & Gamble and the Salk Institute of Biological Studies. Ms. Miller received an MBA degree with a concentration in Marketing from the William E. Simon Graduate School of Business and an MS degree in molecular biology and immunology from the School of Medicine at the University of Rochester. She completed her BS degree in biochemistry and cell biology at the University of California San Diego.

*Melissa Morandi* has been our vice president of quality assurance since January 2006. She joined Anesiva in April 2004 and most recently served as senior director of quality assurance drug and device. From September 2002 to March 2004, Ms. Morandi held director positions in Quality Assurance and Compliance at Biogen Idec

Inc. Previously she spent nine years managing several different quality departments at Genentech, Inc. Prior to that, she worked at Amgen Inc. in Quality Assurance. Before that, Ms. Morandi was employed by the Clinical Laboratory of Saint Francis Hospital, Santa Barbara and Ortho Diagnostics. She holds a B.A. in biochemistry from the University of California at Santa Barbara and an M.S. in Immunology from California State University at Northridge.

*Yvonne Richardson* joined Anesiva as vice president of manufacturing in May 2007. Prior to joining Anesiva, from April 2005 to March 2007, Ms. Richardson worked at Bayer Healthcare Pharmaceuticals as vice president of the Project Management Office. There, she provided strategic direction for the Project Management Office for the Hematology Business. She also was responsible for all strategic projects including capital, new product development and process development for the hematology business. Before Bayer, Ms. Richardson implemented efficient production systems at manufacturing facilities at Hospira, Inc. and Abbott Laboratories. She also was in charge of global development teams for the Renal Division of Baxter Healthcare. Ms. Richardson earned her BA in Chemistry and Philosophy at Knox College and MBA from Lewis University, both in Illinois.

### **Available Information**

We make available, free of charge, through our Internet website, <http://www.anesiva.com>, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically at [www.sec.gov](http://www.sec.gov).

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

#### **Risk Factors Relating to Our Business**

*If we fail to obtain U.S. regulatory approvals for product candidates under development, we will not be able to generate revenue in the U.S. market.*

We must receive FDA approval for each of our product candidates including Adlea before we can commercialize or sell these product candidates in the United States. Even if one of our product candidates is approved by the FDA, the approval may be significantly limited to specific disease indications, patient populations and dosages. The FDA can limit or deny its approval for many reasons, including:

- a product candidate may be found to be unsafe or ineffective;
- regulators may interpret data from preclinical testing and clinical trials differently and less favorably than we do;
- regulators may not approve the manufacturing processes or facilities that we use; and
- regulators may change their approval policies or adopt new regulations.

Failure to obtain FDA approval or any delay or setback in obtaining such approval would:

- adversely affect our ability to market any drugs that we develop and our ability to generate product revenues; and
- impose additional costs and diminish any competitive advantages that we may attain.

As to any product for which marketing approval is obtained, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, such as an adverse side effect, may result in restrictions on the product, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.

If we fail to comply with applicable U.S. regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***If our clinical trials with respect to our product candidates do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these tests or trials, our ability to commercialize products and our financial position will be impaired.***

Clinical development is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, and failure can occur at any stage of testing. Patient enrollment in future clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, and the eligibility criteria for the study and patient compliance. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays, or result in the failure of the trial.

The results of preclinical or clinical studies do not necessarily predict future clinical trial results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Drug-related adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel the program. In addition, we are required by the FDA to conduct additional preclinical studies, including toxicology, while our clinical studies are ongoing.

***To obtain regulatory approval to market our product candidates, we will need to conduct nonclinical studies in animals, and the results of these nonclinical studies may not demonstrate adequate safety or efficacy and, even if they do, the results may not necessarily be predictive of results in human trials.***

As part of the regulatory approval process, we must conduct, at our own expense, nonclinical studies in laboratory animals and clinical trials in humans. The number of nonclinical trials that the regulatory authorities will require varies depending on the product candidate, the disease or condition the product candidate is being developed to address and regulations applicable to the particular product candidate. We may need to perform multiple nonclinical studies using various doses and formulations of our product candidates before we can begin clinical trials, continue clinical trials or obtain approval of our drugs, which could result in delays in our ability to develop or obtain approval of our product candidates. Furthermore, nonclinical results in animal studies are not necessarily predictive of outcomes in human clinical trials. After we have conducted nonclinical studies in animals, we must demonstrate in clinical trials that our product candidates are safe and efficacious for use on humans in order to receive regulatory approval for commercial sale. Even if initial results of nonclinical studies for our product candidates are positive, we may obtain different results in later stages of drug development, including failure to show desired safety and efficacy.

***There may be delays in developing a product candidate as a result of the necessary preclinical studies to assess the safety of the product candidate including its ability to cause cancer and interactions with other drugs.***

We are required to conduct preclinical studies to evaluate the safety of our product candidates including its ability to cause cancer. For example, such studies may be required for Adlea for the treatment of certain indications. Such studies require about three years to complete and report.

***Failure to enroll patients for clinical trials may cause delays in developing the product candidates, and delays in the commencement of clinical testing of the current product candidates could result in increased costs to us and delay our ability to generate revenues.***

We will encounter delays or possibly regulatory rejections if we are unable to enroll enough patients to complete clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Any delays in planned patient enrollment in the future may result in increased costs and delays, which could harm our ability to develop the product candidate.

Delays in the commencement of clinical testing could significantly increase product development costs and delay product commercialization. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

***It may require longer and larger clinical trials to study a product candidate for certain indications such as chronic conditions.***

The time frame of our clinical studies for a product candidate for a chronic condition may also be affected by the International Conference on Harmonisation guidelines that state that at least 1,500 patients must be exposed to the drug prior to submission of a registration application and from 300 to 600 patients be exposed to a new drug for one year. If development of Adlea for pain resulting from musculoskeletal diseases is subject to these guidelines, development for these indications may be longer than a development program for an acute condition such as postsurgical pain. In addition to the time required to conduct these studies, the results of such studies may demonstrate harmful side effects of a product candidate which would impair or prevent our ability to develop such product candidate.

***If third-party clinical research organizations do not perform in an acceptable and timely manner, our clinical trials could be delayed or unsuccessful.***

We do not have the ability to conduct all of our clinical trials independently. We rely on clinical investigators, third-party clinical research organizations and consultants to perform substantially all of these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these third parties do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize our products on a timely basis, if at all. Our agreements are generally cancelable by either party with 30 days notice, with or without cause.

***We have no in-house manufacturing and a limited number of manufacturing personnel and expect to depend on third-party manufacturing.***

We have limited manufacturing facilities, and we have a limited number of personnel with experience in manufacturing any clinical or commercial products or in designing drug manufacturing processes. We are in the process of acquiring manufacturing equipment and certain leasehold modifications that will be located at our contract manufacturer facilities. We have contracted with third-party manufacturers to produce, in collaboration with us, clinical and commercial supplies of our products. We intend to rely substantially on third-party contract manufacturers to manufacture, supply, warehouse and distribute any resulting products. Linde AG acts as the sole supplier for the cylinder of compressed helium gas, a key component in the dispenser for Zingo.

There are a small number of suppliers of the materials which are necessary to manufacture Zingo and, in the case of the cylinder used in Zingo, we rely on a sole supplier. The cylinder of compressed helium gas is a key component in the dispenser for Zingo. We acquire the cylinders for Zingo from PowderMed Limited, a wholly-owned subsidiary of Pfizer, Inc., under a long-term supply agreement. PowderMed Limited is currently our sole supplier and source of cylinders, which are manufactured for it by Linde AG, and to date we have not identified an alternative source. If we are required to seek an alternative source for the cylinders, we might not be successful in establishing an alternative commercial arrangement with a supplier, or if we were successful in finding an alternate supplier, it could be on terms which are less favorable than the current supply agreement with PowderMed Limited. In addition, we currently have no approved supplier of the sealing film for the drug cassette in the dispenser for Zingo. We may not be successful in establishing a commercial arrangement for a supplier for the sealing film.

The contract manufacturers for Zingo need to purchase the materials required for Zingo. Suppliers may not sell these materials to us at the time we need them or on commercially reasonable terms. If our manufacturers or we are unable to purchase these materials or manufacture Zingo on commercially reasonable terms the commercial launch of Zingo would be delayed or there would be a shortage in supply of Zingo, which would harm our ability to generate revenues from the sale of Zingo. If suppliers increase the price of these materials or we cannot otherwise produce Zingo with an acceptable cost of goods, the price for Zingo may increase which may make Zingo a less competitive product for the relief of venipuncture pain. If we change suppliers for any of these materials or any of our current suppliers experience a shutdown or disruption in the facilities used to produce these materials, due to technical, regulatory or other problems, it could harm our ability to manufacture products.

We may in the future elect to manufacture certain of our products in our own manufacturing facilities. We would need to invest additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

***If our third-party manufacturers' facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.***

Our third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of our third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial use or clinical study, the termination of a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition we could be subject to sanctions being imposed on us, including fines, injunctions and civil penalties. Changing manufacturers may require revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and will require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

***Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.***

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or

failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

***Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.***

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we or our foreign marketing partners must obtain separate regulatory approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

***If we do not find collaborators for our product candidates, we may have to reduce or delay our rate of product development and/or increase our expenditures.***

Our strategy to develop, manufacture and commercialize our products may include entering into various relationships with pharmaceutical companies with respect to some programs to advance such programs and reduce our expenditures on such programs. Our product candidates will target highly competitive therapeutic markets in which we have limited experience and expertise. If we are unable to develop this expertise ourselves, we will need to enter into agreements with a biotechnology or pharmaceutical company to provide us with the necessary resources and experience for the development and commercialization of products in these markets. There are a limited number of companies with the resources necessary to develop our future products commercially, and we may be unable to attract any of these firms. A company that has entered into a collaboration agreement with one of our competitors may choose not to enter into a collaboration agreement with us. We may not be able to negotiate any collaboration on acceptable terms or at all. If we are not able to establish collaborative arrangements, we may have to reduce or delay further development of some of our programs and/or increase our expenditures and undertake the development activities at our own expense. If we elect to increase our expenditures to fund our development programs, we will need to obtain additional capital, which may not be available on acceptable terms or at all.

In addition, there have been a significant number of recent business combinations among biotechnology and pharmaceutical companies that have reduced the number of potential future collaborators. If business combinations involving potential collaborators were to occur, the effect could be to diminish, terminate or cause delays in one or more of our product development programs.

***We have no experience selling, marketing or distributing product.***

In order to commence commercial sales of Zingo, or any other product for which we receive regulatory approval, we have established a sales and marketing organization with appropriate technical expertise and distribution capability. At present, we have 15 sales reps and a limited number of marketing employees. While our sales and marketing team is highly experienced, they have not worked together at Anesiva. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- difficulty in retaining adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to, or persuade adequate numbers of, physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage against companies with broader product lines; and
- unforeseen costs associated with creating an independent sales and marketing organization.

***If our third-party promotional partner for Zingo does not perform in an acceptable and timely manner, our commercialization of Zingo could be delayed, less successful or unsuccessful.***

We have entered into a Promotional Agreement with Sagent Pharmaceuticals, Inc. ("Sagent") relating to Zingo. Under the Promotional Agreement, Sagent will undertake certain promotional activities with respect to Zingo in the United States for a period of time. These activities include facilitation of Zingo-related contract negotiations with hospitals and group purchasing organizations, and the management of the warehousing and distribution of Zingo. If Sagent fails to perform these services in an acceptable and timely manner, it could affect our ability to sell Zingo and our revenues may be reduced.

***If we fail to successfully commercialize our single approved product or fail to successfully clinically develop our single product candidate, our revenue will be adversely affected.***

At this time, Zingo is our only approved product and Adlea is our only product candidate being actively developed. Our future revenues, if any, will be derived solely from these two products in the foreseeable future. If commercialization of Zingo or clinical development of Adlea is unsuccessful, our revenues will be adversely affected.

***Our competitors currently offer and may develop therapies that reduce the size of our markets.***

Our business has been characterized by extensive research and development efforts, rapid developments and intense competition. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Our potential products may not compete successfully. If these competitors get to the marketplace before we do with better or less expensive drugs, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it 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. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products to the market.

Our product candidates are intended to compete directly or indirectly with existing drugs. Even if approved and commercialized, our products may fail to achieve market acceptance with hospitals, physicians or patients. Hospitals, physicians or patients may conclude that our potential products are less safe or effective or otherwise less attractive than these existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Zingo, if commercialized, will face significant competition. Two leading products for local anesthesia prior to venipuncture procedures were L.M.X.4<sup>®</sup>, a cream-based product (formerly ELA-MAX, Ferndale Labs), and EMLA<sup>®</sup>, a cream-based product sold by AstraZeneca. EMLA<sup>®</sup> has historically been the market leader, and several generic versions of EMLA<sup>®</sup> that are manufactured by Fougera, Atrix, Geneva, and Hi-Tech Pharmaceuticals were approved by the FDA. These products already have established distribution channels and are well known to physicians and hospitals. A third product, Synera<sup>™</sup>, a topical anesthetic patch, was launched by ZARS/Endo Pharmaceuticals Inc. during 2006. There are additional products including Numby Stuff<sup>®</sup> (Iomed) and LidoSite<sup>®</sup> (Braun-Vyteris) with more rapid onset than the cream-based products above.

Adlea, if approved and commercialized, will face significant competition. For postsurgical pain, morphine administered by infusion pump is a common treatment method. Several other oral, injectable and patch opioids are also used, including Vicodin<sup>®</sup> (Abbott Labs), OxyContin<sup>®</sup> (Purdue Pharma), Ionsys<sup>™</sup> and Duragesic<sup>®</sup> (Johnson & Johnson) and generic versions of Duragesic that are manufactured by Mylan & Sandoz. For later-stage osteoarthritis, in

addition to NSAIDs, and Celebrex® (Pfizer), hyaluronic acid products, including Synvisc® (Genzyme), are injected locally and there is some oral opioid use. For the treatment of tendonitis, glucocorticosteroids are used. TRPV1, which is involved in the transmission of pain signals to the brain and which is affected by Adlea, has become a popular target for the pharmaceutical industry. TRPV1 inhibitors that may also compete with Adlea are being developed by several companies, including Merck-Neurogen, Pfizer-Renovis, Amgen, Schwarz Pharma-Amore Pacific, Purdue Pharma, and PainCeptor. These TRPV1 inhibitors are expected to advance to clinical evaluation shortly. We believe there are other products that are in development that may compete with our current product candidates.

Most of our competitors, including many of those listed above, have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical trials and obtaining regulatory approvals, as well as in manufacturing and marketing pharmaceutical products. As a result, they may achieve product commercialization or patent protection earlier than we can.

***If we fail to obtain an adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.***

The availability and levels of reimbursement by governmental and other third party payors affect the market for our products. The efficacy, safety and cost-effectiveness of our products as well as the efficacy, safety and cost-effectiveness of any competing products will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues would be reduced.

***We have a limited operating history and if we do not generate significant revenues, we will not be able to achieve profitability.***

We have a limited history of operations and we have incurred net losses since our inception. As of December 31, 2007, we had deficit accumulated during the development stage of approximately \$208.8 million. We expect to incur substantial net losses to further develop and commercialize our products and do not know whether or when we will become profitable and may not be able to sustain our operations.

***We will need additional financing, which may be difficult to obtain. If we fail to obtain necessary financing or do so on unattractive terms, our development programs and other operations could be harmed.***

We will require substantial funds to further develop and commercialize our products. We expect to incur significant spending as we expand our development programs and commercialization activities and our future capital requirements will depend on many factors, including:

- the scope and results of our clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for Adlea, and other future product candidates;
- the cost of manufacturing activities;
- the cost of Zingo commercialization activities; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including any litigation costs and the results of such litigation.

Additional financing may not be available when we need it or may not be available on favorable terms. If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail one or more of our research, development or commercial programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preference over our common stock.

***We depend on our officers and key employees, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.***

We are highly dependent on our chief executive officer, John P. McLaughlin and other officers and key employees. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of any of our officers or key employees could delay or prevent the successful enrollment and completion of our clinical trials or the commercialization of Zingo. We do not carry key man life insurance on our officers or key employees.

We have employment agreements with Messrs. McLaughlin, our chief executive officer and Patrick A. Broderick, our vice president and general counsel. Each of our officers and key employees may terminate their employment without notice and without cause or good reason.

In addition, our growth will require hiring a significant number of qualified executive, scientific, regulatory, manufacturing, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Our offices are located in the San Francisco Bay Area, where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

### **Risks Related to Our Industry**

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

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing, and marketing of drugs and related devices. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. In addition, as our product candidates other than Zingo are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity or reduced acceptance of our products in the market.

***Our operations involve hazardous materials and we must comply with environmental laws and regulations, which can be expensive.***

Our research and development activities involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances and store certain low-level radioactive waste at our facility until the materials are no longer considered radioactive. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur

significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

***The life sciences industry is highly competitive and subject to rapid technological change.***

The life sciences industry is highly competitive and subject to rapid and profound technological change. Our present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than we do. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Our existing or prospective competitors may develop processes or products that are more effective than ours or be more effective at implementing their technologies to develop commercial products faster. Our competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before us. Developments by our competitors may render our product candidates obsolete or non-competitive.

We also experience competition from universities and other research institutions, and we frequently compete with others in acquiring technology from those sources. These industries have undergone, and are expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact upon our ability to sell our products profitably. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicare reimbursement has recently been enacted by Congress. Given this legislation's recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. More recently, administrative proposals are pending that would change the method for calculating the reimbursement of certain drugs. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborators or market our products. Such proposals, if enacted, may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

**Risk Factors Relating to Our Intellectual Property**

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

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. Neither we nor our licensors may be able to obtain additional issued patents relating to our technology. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of the term of patent protection we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions

are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any leak of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets.

***If we lose our licenses from PowderMed Limited for Zingo or certain licensees for Adlea, we will not be able to continue development or outlicensing of our current products.***

We are a party to two significant license agreements relating to patents, patent applications and know-how covering the technology relating to Zingo and Adlea. These license agreements impose various diligence, commercialization, royalty and other obligations on us. If we fail to comply with the obligations in the license agreements, the licensor may have the right to terminate the license and we may not be able to market products that were covered by the license.

The license agreement with James N. Campbell, M.D., Richard A. Meyer, M.S. and Marco Pappagallo, M.D. relates to the steps of administering capsaicin for pain reduction utilized in Adlea, and our rights under this agreement can be terminated on 10 days' written notice if we fail to make a payment or fulfill any material obligation under the agreement and the failure is not cured by us within 180 days of receiving notice of such failure. The license agreement with PowderMed Limited, now a wholly-owned subsidiary of Pfizer, Inc., relates to technology underlying Zingo. The agreement with PowderMed Limited can be terminated immediately by either party if the other party ceases to do business in the ordinary course, or assigns all or substantially all of its assets for the benefit of creditors. Either party can also terminate for material breach if not cured within 60 days of notice or if not cured within 30 days of notice if the breach relates to payment provisions. To date, we believe we have met our obligations under all of these agreements.

***We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.***

We may not have rights under some patents or patent applications that would be infringed by technologies that we use in our research, drug targets that we select, or product candidates that we seek to develop and commercialize. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference proceeding declared before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products and technology, we may become so in the future. We are not currently aware of any actual or potential infringement

claim involving our intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

### **Other Risk Factors**

***Anti-takeover defenses that we have in place could prevent or frustrate attempts by stockholders to change the direction or management of the company.***

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third-party from acquiring control of us without the approval of our board of directors. These provisions:

- establish a classified board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance agreement requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

***Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence.***

Our executive officers, directors and principal stockholders, together with their affiliates, own approximately 60.2% of our voting stock, including shares subject to outstanding options based upon shares outstanding as of December 31, 2007. Our executive officers are not affiliated with any of our directors, principal stockholders or their affiliates. These stockholders will likely be able to determine the composition of our board of directors, possess the voting power to approve all matters requiring stockholder approval, including the approval of mergers and acquisitions or other changes in corporate control, and will continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

*If our stock price is volatile, purchasers of our common stock could incur substantial losses.*

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The price for our common stock may be influenced by many factors, including:

- results of our clinical trials;
- failure of any of our product candidates, if approved, to achieve commercial success;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- ability to manufacture our products to commercial standards;
- public concern over our products;
- litigation;
- the departure of key personnel;
- future sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors' perceptions of us; and
- general economic, industry and market conditions.

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

None.

#### **Item 2. Properties**

As of December 31, 2007, we leased an approximately 50,400 square foot office and laboratory space facility in South San Francisco, California for our headquarters and as the base for product support operations and research and development activities. In August 2006, we extended the term of our lease agreement for this facility from July 1, 2007 through November 13, 2010. We also leased an approximately 2,300 square foot office facility in Sunnyvale, California, which we are subleasing through the end of our lease term, March 2008.

In addition, we leased an approximately 6,400 square foot office space facility in West Conshohocken, Pennsylvania for our sales and marketing operations. This lease expires in November 2009. We also leased an approximately 16,000 square foot office space facility in Secaucus, New Jersey, which we vacated in October 2006. This lease expires in July 2009 and as of December 31, 2007 we had not secured a sub-tenant lease for this facility. We believe that our current facilities will be sufficient to meet our needs through the end of 2008.

#### **Item 3. Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings.

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

None.

## PART II

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

Our common stock trades on the Nasdaq Global Market under the symbol "ANSV." As of January 31, 2008 there were approximately 171 stockholders of record of our common stock. The following table sets forth, for the periods indicated, the high and low bid quotations for our common stock as reported by the Nasdaq Global Market.

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2006</b>		
First Quarter .....	\$10.44	\$8.32
Second Quarter .....	\$ 9.47	\$6.51
Third Quarter .....	\$ 7.89	\$6.40
Fourth Quarter .....	\$ 7.87	\$6.31
<b>Year Ended December 31, 2007</b>		
First Quarter .....	\$ 8.71	\$6.70
Second Quarter .....	\$ 8.35	\$5.78
Third Quarter .....	\$ 7.07	\$4.92
Fourth Quarter .....	\$ 7.00	\$3.95

#### Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, capital requirements, covenants in our debt instruments, and such other factors as the board of directors deems relevant.

#### Issuer Purchases of Equity Securities

None.

## Item 6. Selected Financial Data

The following consolidated selected financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K.

	Year ended December 31,					Period from
	2007	2006	2005	2004	2003	March 6, 2001 (Inception) to December 31, 2007
	(in thousands, except share and per share amounts)					
<b>Consolidated Statements of Operations Data:</b>						
Contract revenue	\$ 51	\$ 89	\$ —	\$ —	\$ 100	\$ 389
Operating expenses:						
Research and development	35,660	35,259	19,294	17,169	12,191	131,683
General and administrative	25,722	23,582	17,234	6,468	3,477	80,655
Acquired in-process research and development	—	—	—	—	—	5,716
Total operating expenses	61,382	58,841	36,528	23,637	15,668	218,054
Loss from operations	(61,331)	(58,752)	(36,528)	(23,637)	(15,568)	(217,665)
Gain (loss) on sale of assets	151	(267)	22	—	103	(27)
Interest and other expense	(1,524)	(6)	—	(24)	(107)	(1,667)
Interest and other income	3,422	3,458	1,263	628	86	9,141
Net loss before extraordinary gain	(59,282)	(55,567)	(35,243)	(23,033)	(15,486)	(210,218)
Extraordinary gain	—	—	1,725	—	—	1,725
Net loss	<u>\$ (59,282)</u>	<u>\$ (55,567)</u>	<u>\$ (33,518)</u>	<u>\$ (23,033)</u>	<u>\$ (15,486)</u>	<u>\$ (208,493)</u>
Basic and diluted net loss per common share	<u>\$ (2.12)</u>	<u>\$ (2.69)</u>	<u>\$ (16.89)</u>	<u>\$ (27.68)</u>	<u>\$ (59.75)</u>	
Shares used in computing basic and diluted net loss per common share	<u>28,024,078</u>	<u>20,643,318</u>	<u>1,984,951</u>	<u>832,024</u>	<u>259,182</u>	

See Note 14 to our financial statements for a description of the method used to compute basic and diluted net loss per common share and shares used in computing basic and diluted net loss attributable to common stockholders per share.

	As of December 31,				
	2007	2006	2005	2004	2003
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 90,840	\$ 85,055	\$ 94,913	\$ 39,858	\$ 4,546
Total assets	109,736	95,376	97,917	43,254	7,401
Convertible preferred stock	—	—	—	87,687	32,194
Accumulated deficit	(208,765)	(149,211)	(93,644)	(60,126)	(37,093)
Total stockholders' equity (deficit)	88,514	88,328	89,540	(47,877)	(36,562)

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

*You should read the following discussion and analysis in conjunction with "Item 6. Selected Financial Data," and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K.*

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutic treatments for pain management. Our portfolio of products includes:

- Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, which was approved by the FDA in August to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age.
- Adlea™, a long-acting anesthetic, is being developed for site-specific, moderate to severe pain, and has completed multiple Phase 2 trials in post-surgical, musculoskeletal and neuropathic pain indications. The company is pursuing two indications for Adlea—post-surgical pain and osteoarthritis pain—and is executing on a Phase 3 plan which involves multiple Phase 2 and Phase 3 studies during 2008, some of which are underway.

Zingo and Adlea are different drugs, each with its own mechanism of action. Zingo is comprised of microcrystals of lidocaine delivered into the skin by compressed gas. Zingo employs a proprietary needle-free dispenser. Adlea is a novel non-opioid drug candidate that is a vanilloid receptor 1 agonist, or TRPV1 agonist, based on the compound capsaicin which provides analgesia for between two and three months.

During 2007, we announced the following:

- In February 2007, the FDA acceptance for the filing of the company's New Drug Application (NDA)/ Common Technical Document (eCTD) for marketing clearance of Zingo to treat pain associated with intravenous cannulation and venipuncture procedures in children;
- In March 2007, the commencement of enrollment of adult patients in a Phase 3 clinical study of Zingo to treat pain associated with peripheral venous access procedures;
- In July 2007, results from a Phase 2 study showing that a 1 mg treatment with Adlea in patients with moderate-to-severe osteoarthritis of the knee produced substantial reductions in pain that persisted for up to 12 weeks;
- In August 2007, U.S. Food and Drug Administration (FDA) approval of Zingo to treat pain associated with needle insertion procedures in children;
- In August 2007, the completion of an agreement with Particle Therapeutics Limited granting a specific-use license for delivery of its diabetes drug;
- In September 2007, initiation of a new Phase 2 study of Adlea for post-operative pain in patients undergoing knee replacement surgery/total knee arthroplasty (TKA);
- In October 2007, first patient treated in a Phase 2 study of Adlea for post-operative pain in patients undergoing total hip replacement surgery/total hip arthroplasty (THA);
- In October 2007, a co-promotion and distribution agreement with Sagent Pharmaceuticals for Zingo in U.S. hospitals;
- In October 2007, positive top-line results from pivotal Phase 3 trial of Zingo in adults;
- In October 2007, a cooperative joint venture with Jiangsu Wanbang Biological Pharmaceutical Corporation Co., Ltd., for the establishment of Wanbang Anesiva (Jiangsu) Pharmaceutical Co., Ltd;

- In November 2007, the filing of a shelf registration statement on Form S-3 with the Securities and Exchange Commissions to issue various securities for proceeds in the aggregate amount of up to \$50.0 million;
- In December 2007, the completion of a public offering of 12.3 million shares of our common stock that resulted in approximately \$50 million gross proceeds; and
- In December 2007, the completion of an agreement with Medical Futures Inc. granting a non-exclusive license to Medical Futures for the marketing and distribution of Zingo in Canada.

### **Restructuring Activities**

In connection with the merger with AlgoRx Pharmaceuticals, Inc., or AlgoRx, in December 2005, our board of directors approved a restructuring plan to reduce research costs, realign development efforts and realize operational efficiencies in general and administrative functions. As of December 31, 2005, we had incurred approximately \$439,000 related to the restructuring plan, primarily related to employee severance costs for 19 employees. During the year ended December 31, 2006, we recorded an additional charge of approximately \$881,000 related to the termination of 10 employees. These costs were recorded as a charge in general and administrative expense and research and development expense. We completed the restructuring activities initiated in connection with our merger on September 30, 2006.

In March 2006, we exited a former AlgoRx facility in Sunnyvale, California and recorded an accrual of approximately \$117,000, offset by estimated future sublease income of approximately \$93,000. At December 31, 2007 the remaining exit cost liability was \$3,000. The lease for this facility expires on March 31, 2008.

In October 2006, we announced the closure of a former AlgoRx office space in Secaucus, New Jersey to further reduce ongoing operational costs. As a result, we incurred a charge of approximately \$176,000 primarily related to severance costs for five employees. Also in October 2006, we recorded a charge of approximately \$487,000 related to vacating our office space in Secaucus, New Jersey and discontinuing other office equipment operating leases. In September 2007, we recorded an additional charge of \$579,000 due to the elimination of any future sublease income, as a result of a worsening of the office rental market in Secaucus, New Jersey. The lease related to this office space expires on July 2009 and the leases related to the office equipment expire on June 2007, March 2008, and January 2009.

### **Financial Operations Overview**

#### **Revenue**

We recognized approximately \$51,000 in revenue for the year ended December 31, 2007 related to the license of our drug delivery technology to Particle Therapeutics, LLC and to the non-exclusive license to market and distribute Zingo to Medical Futures Inc.

We do not expect to generate revenue from our product sales or royalties until the second quarter of 2008, if at all. Our goal is to generate revenue from product sales. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the sale of our products to the extent any are successfully commercialized.

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

Our research and development expenses consist primarily of:

- salaries and related expenses for personnel;
- costs of operating facilities and equipment;

- fees paid to regulatory agencies, consultants, and clinical research organizations in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with the clinical trials;
- fees paid to research organizations in conjunction with preclinical studies;
- costs to develop manufacturing processes at third-party manufacturers;
- costs of materials used in research and development;
- upfront and milestone payments under in-licensing agreements;
- consulting fees paid to third parties; and
- depreciation of capital resources used to develop products.

We expense both internal and external research and development costs as incurred. We expect our research and development expenses to increase as we continue to develop our product candidates.

We use our employee and infrastructure resources across several projects, and some costs are not attributable to an individually-named project but rather are directed across these research projects. The following table shows, from inception through December 31, 2007, the total costs associated with Zingo, Adlea, 1207, Avrina and other research and development activities (in thousands):

	Year Ended December 31,					Period from March 6, 2001 (Inception) to December 31, 2007
	2007	2006	2005	2004	2003	
Zingo .....	\$11,102	\$11,722	\$ 5,992	\$ 5,860	\$ 7,129	\$ 48,682
Adlea .....	11,034	4,353	9,775	7,951	4,697	42,222
1207 .....	351	2,291	1,166	2,536	—	6,344
Avrina .....	657	1,678	156	—	—	2,491
Other research and development .....	12,516	15,215	2,205	822	365	31,944
Total .....	<u>\$35,660</u>	<u>\$35,259</u>	<u>\$19,294</u>	<u>\$17,169</u>	<u>\$12,191</u>	<u>\$131,683</u>

We expect that a large percentage of our research and development expenses in the future will be incurred in support of a Phase 2 and Phase 3 trials of Adlea for management of pain following orthopedic surgery and osteoarthritis pain. These expenditures are subject to numerous uncertainties in timing and cost to completion. We test our product candidates in numerous preclinical studies for toxicology, safety, and efficacy. We then conduct early stage clinical trials for each drug candidate. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical trials by us or our future collaborators may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of patients included in the trials;
- the length of time required to enroll suitable patient subjects;
- the number of sites that participate in the trials;
- the number of doses that patients receive;
- the duration of patient follow-up;
- the phase of development the product is in; and
- the efficacy and safety profile of the product.

The FDA has approved Zingo to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. We have submitted a sNDA to expand the treatable patient population for Zingo to include adults. The FDA has not approved that sNDA and foreign regulatory have not approved Zingo for any patient population. Adlea is still being studied in clinical trials and has not yet received approval by the FDA or any foreign regulatory authority. In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that our clinical data establish the safety and efficacy of our drug candidates.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will receive cash inflows from the commercialization and sale of a product.

### **General and Administrative Expenses**

General and administrative expenses consist primarily of compensation, including stock-based compensation, for employees in executive and operational functions, including finance, business development and marketing. Other significant costs include facilities costs and professional fees for marketing, accounting and legal services, including legal services associated with obtaining and maintaining patents.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to the financial statements included in this annual report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of the financial statements.

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

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), using the modified prospective transition method. In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

Prior to the adoption of SFAS 123(R), we accounted for employee stock options using the intrinsic value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB No. 25, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in our consolidated statement of operations, other than as related to options granted to employees and directors at an exercise price lower than the fair value of the underlying stock at the date of grant.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. We value share-based awards using the Black-Scholes option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our consolidated statement of operations.

Stock-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during that period. We use the straight-line single option method to allocate stock-based compensation expense. As stock-based compensation expense recognized in the consolidated statement of operations for the year ended December 31, 2006 are based on awards ultimately expected to vest, they have been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to January 1, 2006, we accounted for forfeitures as they occurred.

Prior to the adoption of SFAS 123(R), stock compensation expense, which is a non-cash charge, related to stock option grants at exercise prices below the deemed fair value of the underlying common stock and from grants of restricted stock. Stock compensation is amortized on a straight-line basis over the vesting period of the underlying option, generally four years for stock options and two to three years for restricted stock.

#### ***Clinical Trial Accounting***

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

#### ***Marketable Securities Accounting***

We invest our excess cash in money market funds and in highly liquid debt instruments of the U.S. government, its agencies and municipalities and corporate notes. All highly liquid investments with stated maturities of 90 days or less from date of purchase are classified as cash equivalents; highly liquid investments with stated maturities of greater than 90 days are classified as marketable securities.

We determine the appropriate classification of investments in debt securities at the time of purchase. Cash equivalents and marketable securities are classified as available-for-sale securities as we do not intend to hold securities with stated maturities greater than twelve months until maturity. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income or expense.

We periodically evaluate investments for impairment and write-down if we estimate that the impairment is other than temporary. We take into account general market conditions, changes in economic environment as well as specific investment attributes, such as credit downgrade or illiquidity for each investment, to estimate either the fair value of our investments and to determine whether impairment is other than temporary.

### *Inventories*

Inventories are stated at the lower of cost or market and consist primarily of material and certain contract manufacturing costs for the production of Zingo that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires us to estimate obsolete or excess inventory based on analysis of future demand for Zingo. If inventory costs exceed expected market value due to obsolescence, impairment charge may be recorded as deemed necessary by management for the difference between the cost and the market value. There were no impairment charges reserved at December 31, 2007.

### **Results of Operations**

#### *Comparison of the Years Ended December 31, 2007, 2006 and 2005*

##### *Revenues*

	<u>Year Ended December 31,</u>			<u>2007 to 2006 Change</u>		<u>2006 to 2005 Change</u>	
	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>\$</u>	<u>%</u>	<u>\$</u>	<u>%</u>
Revenues .....	\$51	\$89	\$—	\$(38)	(43)%	\$89	n/m

n/m: not meaningful

Revenue in 2007 resulted primarily from recording of drug delivery technology license revenue from Particle Therapeutics, LLC. Revenue in 2006 resulted from recording of database license revenue from Lumen Therapeutics, LLC. There were no revenues in 2005. We anticipate we will generate revenue from on-going out-licensing collaborations and from the sales of Zingo in 2008.

##### *Research and Development Expenses*

The following table summarizes our research and development expenses:

	<u>Year Ended December 31,</u>			<u>2007 to 2006 Change</u>		<u>2006 to 2005 Change</u>	
	<u>2007</u>	<u>2006</u>	<u>2005</u>	<u>\$</u>	<u>%</u>	<u>\$</u>	<u>%</u>
Research and development expenses . . . .	\$35,660	\$35,259	\$19,294	\$401	1%	\$15,965	83%

The increase in research and development expenses for 2007 compared to 2006 was primarily due to the following:

- Increase in clinical trial costs of \$2.5 million due to expenses to complete Phase 3 Zingo trial in adults and expenses for Phase 2 Adlea trials for post-surgical and osteoarthritis pain;
- Increase in compensation and employee related expenses of \$0.8 million offset by decrease in stock based compensation expenses of \$1.6 million due to lower priced options in 2007 and charges associated with acceleration of stock option vesting for terminated employees in 2006;
- Decrease in professional services of \$0.9 million reflecting in part lower expenses in clinical and preclinical of \$1.8 million offset by increase in manufacturing professional services of \$1.2 million related to third party manufacturing development expenses for Zingo;
- Increase in other research and development expenses of \$0.1 million; and
- Decrease in facilities and related expenses of \$0.5 million due to lower allocation of facilities overhead.

The increase in research and development expenses for 2006 compared to 2005 was primarily due to the following:

- Increase in compensation expense and employee related expenses of \$7.5 million which included stock-based compensation of \$2.5 million due to the adoption of SFAS 123(R);
- Increase in clinical consulting costs of \$3.0 million partially offset by a decrease of \$2.6 million in clinical trial costs. Clinical trial costs in 2006 include \$0.9 million for New Drug Application fees for Zingo;
- Increase in manufacturing and preclinical costs of \$3.8 million, primarily in support of Zingo; and
- Increase in facilities and related expenses of \$4.2 million due to larger research dedicated facilities in 2006 as a result of the merger.

In 2008, we expect that our research and development expenses will increase over 2007 levels due to pre-clinical development expenses in support of Adlea, post-surgical and osteoarthritis clinical trial costs for Adlea, and an increase in the number of employees.

*Selling, General, and Administrative Expenses*

The following table summarizes our general and administrative expenses:

	Year Ended December 31,			2007 to 2006 Change		2006 to 2005 Change	
	2007	2006	2005	\$	%	\$	%
	(in thousands, except percentages)						
General and administrative expenses .....	\$25,722	\$23,582	\$17,234	\$2,140	9%	\$6,348	37%

The increase in general and administrative expenses for 2007 compared to 2006 was primarily due to the following:

- Increase in professional services of \$3.0 million primarily in marketing due to Zingo pre-launch/launch activities;
- Decrease in stock based compensation of \$1.4 million due to lower priced options in 2007 and charges associated with acceleration of stock option vesting for terminated employees in 2006;
- Increase in other corporate expenses of \$0.2 million which includes approximately \$0.1 million for FDA product and establishment fees; and
- Increase in facilities and related expenses of \$0.3 million primarily due to the additional adjustment of exit cost of our New Jersey office and the expansion of our sales and marketing office in Conshohocken, Pennsylvania.

The increase in general and administrative expenses for 2006 compared to 2005 was primarily due to the following:

- Increase in compensation expense and employee related expenses of \$4.0 million reflecting increased personnel and related costs of \$4.3 million and increased stock-based compensation of \$5.3 million due to the adoption of SFAS 123(R), partly offset by a decrease of \$5.6 million related to a retention bonus payout to AlgorX employees and one director in 2005;
- Increase in professional, legal, consulting, and other corporate expenses of \$4.5 million offset by a decrease of \$1.2 million of financing costs that were expensed in 2005 due to the withdrawal of AlgorX's initial public offering; and
- Decrease in facilities and related expenses of approximately \$1.0 million due to larger research facilities in 2006 as a result of the merger to which proportionately higher facilities overhead were allocated.

In 2008, we expect that our selling, general, and administrative expenses will increase over 2007 levels due to costs in support of our launch efforts for Zingo including building of a sales force.

*Interest and Other Income.* Interest and other income was \$3.4 million in 2007, compared to \$3.5 million in 2006, and \$1.3 million in 2005. The decrease of \$0.1 million in 2007 was primarily due to lower average cash and marketable securities' balances. The increase of \$2.2 million in 2006 was due to higher interest rates and higher average cash and marketable securities' balances.

*Interest and Other Expense.* Interest and other expense was \$1.5 million in 2007, compared to approximately \$6,000 in 2006, and none in 2005. The increase of \$1.5 million in 2007 was primarily due to the write down of two investments of \$1.3 million and interest paid on our equipment line of credit of \$0.2 million. The \$6,000 in 2006 was due to interest paid on our equipment line of credit.

## **Income Taxes**

As of December 31, 2007, we had net operating loss and research carryforwards for federal income taxes of \$84.9 million and approximately \$46,500, respectively. If not utilized, federal net operating loss carryforwards will begin to expire in 2018. We completed a study of our tax attributes through December 31, 2007 under the Section 382 of the Internal Revenue Code, which resulted in significant limitation of net operating losses and credits prior to utilization.

As of December 31, 2007 and 2006, we had deferred tax assets representing the benefit of net operating loss carryforwards and certain start-up costs capitalized for tax purposes. We did not record a benefit for the deferred tax assets because realization of the benefit was uncertain and, accordingly, a valuation allowance is provided to offset the deferred tax assets.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

To date, we have funded our operations primarily through the sale of equity securities. As of December 31, 2007, we had raised \$182.3 million of cash proceeds from the sale of equity securities, including promissory notes that were converted into preferred stock, net of offering expenses.

In June 2006, we entered into a stock purchase agreement with Azimuth Opportunity, Ltd for a two-year commitment of up to \$30.0 million. As of December 2007, we had received a total of \$4.1 million of cash proceeds from the sale of 617,898 shares of our common stock to Azimuth Opportunity, Ltd. and have approximately \$25.9 million available for future draws.

In August 2007, we entered into an equipment loan and security agreement with General Electric Capital Corporation, GECC, with respect to the financing of laboratory and manufacturing equipment in an amount up to \$15.0 million. We borrowed approximately \$6.6 million and \$4.4 million under the agreement on August 30, 2007 and November 30, 2007, respectively. We may borrow against qualified purchases of eligible equipment expected through May 31, 2008. Each borrowing will be evidenced by a promissory note and will be solely secured by the financed equipment. The promissory notes for the two borrowings are repayable over 42 months and bear a fixed interest rate of 9.91% per annum. The first six payments under the promissory notes are interest payments and the next 36 payments are both interest and principal payments. The loan and security agreement contains certain restrictive covenants relating primarily to the financed equipment and additional indebtedness. The loan and security agreement also contains provisions permitting the lender to accelerate the loan if we are in default. A default includes a failure to pay any amount due under the debt documents which is not cured, a breach of any other obligations under the debt documents which is not cured, and an event or development which could reasonably be expected to have a material adverse effect on it.

In December 2007, we issued 12,345,679 shares of our common stock to selected institutional investors in a common stock offering for which we received approximately \$47.7 million of net cash proceeds.

As of December 31, 2007, we had \$90.8 million in cash, cash equivalents and marketable securities as compared to \$85.1 million as of December 31, 2006, an increase of \$5.7 million. This increase resulted primarily from the net cash proceeds generated from the issuance of our common stock of \$51.4 million, issuance of equipment loan from General Electric Capital Corporation of \$10.8 million offset by the use of cash in operating activities of \$48.2 million and the building of manufacturing equipment to produce Zingo of \$7.3 million and loss on marketable securities of \$1.3 million.

### **Cash Flows**

The following table summarizes our statement of cash flows (in millions):

	Year Ended December 31,		
	2007	2006	2005
Cash flows provided by (used in):			
Operating activities	\$(48.2)	\$(44.6)	\$(25.5)
Investing activities	30.3	8.4	29.0
Financing activities	62.3	42.9	22.7
Net increase in cash and cash equivalents	<u>\$ 44.4</u>	<u>\$ 6.7</u>	<u>\$ 26.2</u>

#### *Cash Flows from Operating Activities.*

Net cash used in operating activities was \$48.2 million in 2007, \$44.6 million in 2006, \$25.5 million in 2005. The net increase in cash used from operating activities from 2006 to 2007 of \$3.6 million was primarily due to the increase in net loss of \$3.7 million and decrease in working capital of \$2.3 million, offset by change in non-cash items of \$3.0 million decrease in stock-based compensation, \$1.3 million increase in write down of marketable securities, and \$0.4 million increase in gain on disposal of equipment. The increase in net cash used in operating activities from 2005 to 2006 of \$19.1 million was primarily due to the increase in net loss of \$22.0 million and in working capital of \$2.4 million, offset by change in non-cash items of \$8.4 million increase in stock-based compensation, \$4.8 million decrease in retention bonus costs related to AlgorX merger in 2005 and an extraordinary gain related to excess purchase value paid for Anesiva over net assets acquired of \$1.7 million in 2005.

#### *Cash Flows from Investing Activities.*

Net cash provided by investing activities was \$30.3 million in 2007, \$8.4 million in 2006, and \$29.0 million in 2005. The increase in net cash provided by investing activities of \$21.9 million was primarily due to a net increase in proceeds from the sale of marketable securities of \$20.7 million and the decrease in purchases of equipment of \$1.1 million, primarily for the manufacturing of Zingo, and increase in proceeds from disposal of equipment of \$0.1 million. The decrease in net cash provided by investing activities of \$20.6 million from 2005 to 2006 was primarily due to a net decrease in proceeds from the sale of marketable securities of \$12.4 million and an increase in purchases of equipment of \$8.2 million, primarily for the manufacturing of Zingo.

#### *Cash Flows from Financing Activities.*

Net cash provided by financing activities was \$62.3 million in 2007, \$42.9 million in 2006, and \$22.7 million in 2005. The increase in cash provided by financing activities from 2006 to 2007 of \$19.4 million was primarily due to the increase in sales of common stock of \$8.4 million, proceeds from an equipment loan and security agreement with General Electric Capital Corporation of \$10.8 million, and increase of \$0.2 million in

capital lease obligations. The increase in cash provided by financing activities from 2005 to 2006 of \$20.2 million was primarily due to the increase in sales of common stock of \$43.0 million, which included \$41.6 million in net proceeds from our registered direct offering and \$1.0 million in proceeds from Azimuth Opportunity, Ltd., offset by cash acquired in 2005 of \$22.6 million as a result of the merger between Anesiva and AlgoRx and the repayment of debt for \$0.2 million.

#### ***Credit Facility and Stock Purchase Agreement***

In August 2007, we entered into an equipment loan and security agreement with General Electric Capital Corporation with respect to the financing of laboratory and manufacturing equipment in an amount up to \$15.0 million. At December 31 2007, we had borrowed approximately \$11.0 million under the loan and security agreement. The remainder of approximately \$4.0 million is available for future drawdowns.

In June 2006, we entered into a stock purchase agreement with Azimuth Opportunity, Ltd for a two-year commitment of up to \$30.0 million. As of December 2007, we have received a total of \$4.1 million of cash proceeds from the sale of 617,898 shares of our common stock to Azimuth Opportunity, Ltd. and have approximately \$25.9 million available for future draws.

#### ***Operating Capital and Capital Expenditure Requirements***

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

- the progress of preclinical development and laboratory testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- delays that may be caused by evolving requirements of regulatory agencies;
- the number of product candidates we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization;
- the acquisition of technologies, products and other business opportunities that require financial commitments; and
- our revenues, if any, from successful development and commercialization of our products.

We believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our activities into 2009. Until we can generate significant cash from our operations, we expect to continue to fund our operations with our existing cash, cash equivalent and marketable securities. If we need to raise funds in the future, we may be required to raise those funds through public or private financings, strategic relationships or other arrangements. The sale of additional equity and debt securities may result in additional dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

### **Contractual Obligations**

Our outstanding contractual obligations relate to our facilities leases and obligations under our agreement with our third-party contract manufacturer. Our contractual obligations as of December 31, 2007 were as follows (in millions):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than One Year</u>	<u>One to Three Years</u>	<u>Four to Five Years</u>	<u>After Five Years</u>
Equipment Financing .....	\$13.0	\$3.4	\$ 8.5	\$ 1.1	\$—
Operating Leases .....	6.1	2.3	3.8	—	—
Total contractual cash obligations .....	<u>\$19.1</u>	<u>\$5.7</u>	<u>\$12.3</u>	<u>\$ 1.1</u>	<u>\$—</u>

Under all of our license agreements, we could be required to pay up to a total of approximately \$1.0 million in payments for milestones such as the initiation of clinical trials and the granting of patents. As of December 31, 2007, we incurred approximately \$2.9 million of milestone charges, including approximately \$1.4 million of cash payments and approximately \$1.5 million of stock compensation, for the execution of agreements, patent approvals and the initiation of U.S. clinical trials. Milestone payments will also be due upon the first administration to a subject using licensed technology in a Phase 1 clinical trial, the first administration to a subject using licensed technology in a Phase 3 clinical trial and FDA approval of Adlea in addition to sales milestones and royalties payable on commercial sales if any occur. Dr. James N. Campbell, who has been a member of the Board of Anesiva since June 29, 2007, is one of the three licensors of Adlea.

We have also entered into letters of credit totaling \$658,000 securing our operating lease obligations. We are required to set aside cash as collateral. At December 31, 2007, we had \$658,000 in certificates of deposit designated as restricted cash, which is not available for use in current operations, of which \$68,000 was included as prepaid expenses and other current assets.

In May 2006, we entered an agreement with Mikron Corporation to purchase an automated system for assembling the powder intradermal injection delivery device for Zingo. Pursuant to the agreement, we will pay Mikron Corporation up to an aggregate of \$3.4 million upon the achievement of certain milestones. The agreement will continue until the completion of the assembly system. As of December 31, 2007, we have paid \$3.4 million to Mikron Corporation and have completed our contractual agreement with Mikron.

In August 2006, we entered an agreement with GlaxoSmithKline to extend the term of the lease agreement for our headquarter office in South San Francisco, California from June 1, 2007 through November 13, 2010.

In March 2007, we amended our existing lease agreement with Eight Tower Bridge Development Associates to lease an additional 3,658 square feet for our marketing office in Pennsylvania and the lease will expire in November 2009.

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

At December 31, 2007 and 2006, we did not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purposes entities, which are typically established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

## Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB issued SFAS No. 157, *Fair Value Measurement*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The adoption of SFAS157 did not have a material impact on financial statements for the year ended December 31, 2007.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 allows entities to voluntarily choose, at specified election dates, to measure many financial assets and financial liabilities (as well as certain non-financial instruments that are similar to financial instruments) at fair value, or the fair value option. The election is made on an instrument-by-instrument basis and is irrevocable. If the fair value option is elected for an instrument, SFAS No. 159 specifies that all subsequent changes in fair value for that instrument shall be reported in earnings. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are currently evaluating the effect that SFAS No. 159 will have on our consolidated financial statements, should we decide to adopt its provisions.

In June 2007, the FASB ratified EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. We are currently evaluating the impact of the pending adoption of EITF 07-3 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*. SFAS No. 160 changes the way the consolidated income statement is presented. It requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. This statement also requires expanded disclosures in the consolidated financial statements that clearly identify and distinguish between the interests of the parent's owners and the interests of the noncontrolling owners of a subsidiary. Those expanded disclosures include a reconciliation of the beginning and ending balances of the equity attributable to the parent and the noncontrolling owners and a schedule showing the effects of changes in a parent's ownership interest in a subsidiary on the equity attributable to the parent. SFAS No. 160 is effective as of the beginning of an entity's first fiscal year that begins after December 15, 2008. We are currently evaluating the effect that SFAS No.160 will have on its consolidated financial statements.

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

Our exposure to market risk is principally limited to our cash equivalents and investments that have maturities of less than two years. We do not use or hold derivative financial instruments. We maintain an investment portfolio of investment grade, liquid debt securities that limit the amount of credit exposure to any one issue, issuer or type of instrument. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are therefore subject to interest rate risk. We currently do not hedge interest rate exposure. If market interest rates were to increase by 100 basis points, or 1 percent from December 31, 2007 levels, the fair value of our portfolio would decline by approximately \$1,000. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes ending fair values include principal plus accrued interest.

In August 2007, \$2.9 million invested in two AAA-rated auction rate securities failed to settle in auctions. The failures resulted in the interest rate on these investments resetting at higher rates, one-month Libor plus 50 or 125 basis points. We concluded that the impairment for both securities was other-than-temporary. At September 30, 2007 we had written-down the carrying amount for one investment to \$1.8 million and recognized a loss of \$160,000 in the three months ended September 30, 2007. In November 2007, we sold that security for \$1.6 million, and realized an additional loss of \$195,000. At September 30, 2007 and for the three months ended December 31, 2007, we did not receive an offer from the issuer of the other AAA-rated security that was carried at \$900,000 prior to its failed auction in August 2007. We do not foresee that we will be able to receive any bid in less than six months from the date that instrument auction failed. We continue to conclude that the impairment for this security is other-than-temporary and we are maintaining the carrying amount for that investment to \$0. We recognized a loss of \$900,000 in the three months ended September 30, 2007. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate the lack of liquidity on this investment will affect our ability to operate our business as usual. At December 31, 2007, this investment continues being rated AAA and is paying interest at December 31, 2007. Should this auction rate security reset or trade again due to improvements in the corporate debt market, we would then be able to sell it. We have reviewed all other investments we owned at December 31, 2007 for impairment and concluded that their carrying value approximated their fair value.

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

The financial statements required by this item are submitted as a separate section of this Annual Report on Form 10-K. See Item 15 of Part IV.

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

None.

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

##### *Evaluation of disclosure controls and procedures.*

Based on their evaluation as of December 31, 2007, our chief executive officer and chief financial officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective.

##### *Management's 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 Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2007, our internal control over financial reporting was effective based on these criteria. The Company's independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an audit report on the Company's internal control over financial reporting. The report on the audit of internal control over financial reporting appears below.

##### *Changes in internal controls.*

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

*Limitations on the effectiveness of controls.*

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are 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 Anesiva have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Anesiva, Inc.

We have audited Anesiva, Inc.'s internal controls 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 (the COSO criteria). Anesiva, Inc.'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. 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, testing and evaluating the design and operating effectiveness of internal control, based on the assessed risk, and 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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, Anesiva, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Anesiva, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 and for the period from March 6, 2001 (inception) to December 31, 2007 of Anesiva, Inc. and our report dated March 14, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 14, 2008

**Item 9B. Other Information**

None.

## PART III

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

Information concerning our directors will be contained in our definitive Proxy Statement with respect to our 2008 Annual Meeting of Stockholders, to be held on May 8, 2008, under the caption "Proposal 1—Election of Directors" and is incorporated by reference into this Annual Report on Form 10-K. Information concerning our Audit Committee and Financial Expert is incorporated by reference to the section entitled "Audit Committee" to be contained in our definitive Proxy Statement. Information concerning procedures for recommending directors is incorporated by reference to the section entitled "Nominating and Corporate Governance Committee" to be contained in our definitive Proxy Statement. Information concerning our Executive Officers and Key Employees is set forth under "Executive Officers and Key Employees" in Part I of this Annual Report on Form 10-K and is incorporated herein by reference. Information concerning compliance with Section 16(a) of the Securities and Exchange Act of 1934 is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance," to be contained in our definitive Proxy Statement. Information concerning our code of conduct is incorporated by reference to the section entitled "Code of Conduct," to be contained in our definitive Proxy Statement.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2008 Annual Meeting of Stockholders, to be held on May 8, 2008, under the caption "Executive Compensation," and is hereby incorporated by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2008 Annual Meeting of Stockholders, to be held on May 8, 2008, under the caption "Security Ownership of Certain Beneficial Owners and Management" and is hereby incorporated by reference.

### **Item 13. Certain Relationships and Related Transactions**

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2008 Annual Meeting of Stockholders, to be held on May 8, 2008, under the caption "Transactions with Related Persons," and is hereby incorporated by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2008 Annual Meeting of Stockholders, to be held on May 8, 2008, under the caption "Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm," and is hereby incorporated by reference.

**PART IV**

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

(a) The following documents are filed as part of this Annual Report on Form 10-K:

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1. Financial Statements .....	50
2. Report of Independent Registered Public Accounting Firm .....	51
3. Notes to Financial Statements .....	58
4. Financial Statement Schedules—None.	
5. Exhibits—See Exhibit Index	

(b) Exhibits

See Item 15(a) above.

(c) Financial Statement Schedule

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

**Anesiva, Inc.**  
**Index to Consolidated Financial Statements**

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Consolidated Statement of Stockholders' Equity (Deficit) .....	54
Consolidated Statements of Cash Flows .....	57
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Anesiva, Inc.

We have audited the accompanying consolidated balance sheets of Anesiva, Inc. as of December 31, 2007 and 2006 and the related consolidated statements of operations and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007, and for the period from March 6, 2001 (inception) to December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Anesiva, Inc. at December 31, 2007 and 2006 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, and for the period from March 6, 2001 (inception) to December 31, 2007 in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, in 2006, Anesiva, Inc. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", in 2007, Anesiva, Inc. changed its method of accounting for sabbatical leave in accordance with guidance provided in Emerging Issues Task Force Issue No. 06-2, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43", and its method of accounting for uncertainty in income taxes in accordance with guidance provided in Statement of Financial Accounting Standards No. 48, "Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109."

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Anesiva, Inc.'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 and our report dated March 14, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 14, 2008

**Anesiva, Inc.**  
**(a development stage company)**  
**(In thousands, except share and per share amounts)**

**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2007	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 90,840	\$ 46,454
Marketable securities .....	—	38,601
Prepaid expenses and other current assets .....	1,666	1,153
Inventories .....	559	—
Total current assets .....	93,065	86,208
Property and equipment, net .....	15,276	8,446
Restricted cash .....	590	624
Other assets .....	805	98
Total assets .....	\$ 109,736	\$ 95,376
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 3,370	\$ 2,839
Accrued clinical liabilities .....	1,219	84
Accrued compensation .....	2,301	2,277
Other accrued liabilities .....	2,929	1,631
Current portion of long term debt .....	2,356	—
Total current liabilities .....	12,175	6,831
Long-term debt, net of current portion .....	8,485	—
Long-term deposit .....	—	8
Other long-term liabilities .....	562	209
Commitments		
Stockholders' equity:		
Common stock, \$0.001 par value, 100,000,000 shares authorized at December 31, 2007 and 2006; 40,378,413 and 27,300,581 shares outstanding at December 31, 2007 and 2006, respectively .....	40	27
Additional paid-in capital .....	297,239	237,534
Accumulated other comprehensive gain .....	—	(22)
Deficit accumulated during the development stage .....	(208,765)	(149,211)
Total stockholders' equity .....	88,514	88,328
Total liabilities and stockholders' equity .....	\$ 109,736	\$ 95,376

See accompanying notes.

**Anesiva, Inc.**  
**(a development stage company)**  
**(In thousands, except share and per share amounts)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,			Period from
	2007	2006	2005	March 6, 2001 (inception) to December 31, 2007
Contract revenues .....	\$ 51	\$ 89	\$ —	\$ 389
Costs and expenses:				
Research and development .....	35,660	35,259	19,294	131,683
General and administrative .....	25,722	23,582	17,234	80,655
Acquired in-process research and development and other .....	—	—	—	5,716
Total costs and expenses .....	61,382	58,841	36,528	218,054
Loss from operations .....	(61,331)	(58,752)	(36,528)	(217,665)
Gain (loss) on sale of assets .....	151	(267)	22	(27)
Interest and other expense .....	(1,524)	(6)	—	(1,667)
Interest and other income .....	3,422	3,458	1,263	9,141
Loss before extraordinary gain .....	(59,282)	(55,567)	(35,243)	(210,218)
Extraordinary gain .....	—	—	1,725	1,725
Net loss .....	<u>\$ (59,282)</u>	<u>\$ (55,567)</u>	<u>\$ (33,518)</u>	<u>\$(208,493)</u>
Basic and diluted net loss per common share .....	<u>\$ (2.12)</u>	<u>\$ (2.69)</u>	<u>\$ (16.89)</u>	
Weighted average shares outstanding—basic and diluted .....	<u>28,024,078</u>	<u>20,643,318</u>	<u>1,984,951</u>	

See accompanying notes.

**Anesiva, Inc.**  
(a development stage company)  
(In thousands, except share and per share amounts)

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)**  
Period from March 6, 2001 (inception) to December 31, 2007

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Other Comprehensive Gain (Loss)	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Balance at March 6, 2001 (inception)	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of common stock to founders for \$0.001 per share in March 2001	150,000	—	1	—	—	—	1
Issuance of common stock upon exercise of stock options in April 2001	23,800	—	24	—	—	—	24
Net loss and comprehensive loss	—	—	—	—	—	(1,416)	(1,416)
Balance at December 31, 2001	173,800	—	25	—	—	(1,416)	(1,391)
Issuance of common stock upon exercise of stock options in March 2002	10,150	—	10	—	—	—	10
Issuance of common stock for acquisition of Powderlect Technologies, Inc. in March 2002	152,615	—	229	—	—	—	229
Stock-based compensation resulting from stock options granted to non-employees	—	—	66	—	—	—	66
Net loss and comprehensive loss	—	—	—	—	—	(20,191)	(20,191)
Balance at December 31, 2002	336,565	—	330	—	—	(21,607)	(21,277)
Issuance of common stock upon exercise of stock options in 2003	4,725	—	6	—	—	—	6
Accrued interest costs	—	—	107	—	—	—	107
Deferred compensation related to stock options	—	—	156	—	(156)	—	—
Non-cash compensation	—	—	66	—	—	—	66
Repurchase of common stock	—	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	13	—	13
Stock-based compensation resulting from stock options granted to non-employees	—	—	9	—	—	—	9
Net loss and comprehensive loss	—	—	—	—	—	(15,486)	(15,486)
Balance at December 31, 2003	341,290	—	674	—	(143)	(37,093)	(36,562)
Issuance of common stock	160,000	—	1,536	—	—	—	1,536
Deferred compensation related to stock options	—	—	9,582	—	(9,582)	—	—
Exercise of stock options	2,428	—	4	—	—	—	4
Conversion of Series B convertible preferred stock to common stock	616,615	1	8,015	—	—	—	8,016
Non-cash interest expense	—	—	24	—	—	—	24
Amortization of deferred compensation	—	—	—	—	2,164	—	2,164
Stock-based compensation resulting from stock options granted to non-employees	—	—	24	—	—	—	24
Net loss	—	—	—	—	—	(23,033)	(23,033)
Other comprehensive loss	—	—	—	(50)	—	—	(50)
Total comprehensive loss	—	—	—	(50)	—	—	(50)
Balance at December 31, 2004 (carried forward)	1,120,333	1	19,859	(50)	(7,561)	(60,126)	(47,877)

**Anesiva, Inc.**  
(a development stage company)  
(In thousands, except share and per share amounts)

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)—(Continued)**  
Period from March 6, 2001 (inception) to December 31, 2007

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Other Comprehensive Gain (Loss)	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Balance at December 31, 2004 (brought forward)	1,120,333	1	19,859	(50)	(7,561)	(60,126)	(47,877)
Exercise of stock options	62,293	—	93	—	—	—	93
Issuance of common stock pursuant to merger, net cancellations of AlgoRx common stock	18,379,888	18	163,210	—	—	—	163,228
Reversal of AlgoRx's deferred compensation	—	—	(5,676)	—	5,676	—	—
Deferred compensation assumed related to stock options	—	—	645	—	(645)	—	—
Amortization of deferred compensation	—	—	—	—	1,958	—	1,958
Retention bonus	511,410	1	4,827	—	—	—	4,828
Repricing of options	—	—	47	—	—	—	47
Extension of directors' option exercisability	—	—	150	—	—	—	150
Acceleration of vesting of employee stock options	—	—	63	—	—	—	63
Stock-based compensation resulting from stock options granted to non-employees	—	—	619	—	—	—	619
Net loss	—	—	—	—	—	(33,518)	(33,518)
Other comprehensive loss	—	—	—	(51)	—	—	(51)
Total comprehensive loss	—	—	—	(51)	—	—	(51)
Balance at December 31, 2005	20,073,924	20	183,837	(101)	(572)	(93,644)	89,540
Elimination of deferred compensation upon adoption of FAS123(R)	—	—	(572)	—	572	—	—
Issuance of common stock upon exercise of stock options	8,739	—	143	—	—	—	143
Issuance of common stock under the Azimuth Opportunity stock purchase agreement net of issuance costs of \$38 in September 2006	154,837	—	962	—	—	—	962
Issuance of common stock under a registered direct offering, net issuance costs of \$3,013 in November 2006	7,000,000	7	41,635	—	—	—	41,642
Issuance of common stock under the employee stock purchase plan	38,956	—	260	—	—	—	260
Stock-based compensation resulting from stock options granted to employees	—	—	10,937	—	—	—	10,937
Compensation expense resulting from restricted stock awards to employees, net of cancellation of awards	(375)	—	140	—	—	—	140
Stock-based compensation resulting from stock options granted to non-employees	—	—	63	—	—	—	63
Issuance of restricted stock awards to non-employees and related compensation expenses from outstanding awards	24,500	—	129	—	—	—	129
Net loss	—	—	—	—	—	(55,567)	(55,567)
Other comprehensive gain	—	—	—	79	—	—	79
Total comprehensive loss	—	—	—	79	—	—	(55,488)
Balance at December 31, 2006 (carried forward)	27,300,581	\$ 27	\$237,534	\$ (22)	\$ —	\$ (149,211)	\$ 88,328

Anesiva, Inc.

(a development stage company)  
(In thousands, except share and per share amounts)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)—(Continued)  
Period from March 6, 2001 (inception) to December 31, 2007

	Common Stock		Additional Paid-In Capital	Other Comprehensive Gain (Loss)	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at December 31, 2006 (brought forward)	27,300,581	\$ 27	\$237,534	\$ (22)	\$—	\$(149,211)	\$ 88,328
Issuance of common stock upon exercise of stock options	42,412	—	292	—	—	—	292
Issuance of common stock under the Azimuth Opportunity stock purchase agreement net of issuance costs of \$91 in June and August 2007	463,061	1	3,027	—	—	—	3,028
Issuance of common stock under shelf offering net issuance costs of \$298 in December 2007	12,345,679	12	47,683	—	—	—	47,695
Issuance of common stock under the employee stock purchase plan	73,610	—	419	—	—	—	419
Stock-based compensation resulting from stock options granted to employees	—	—	7,735	—	—	—	7,735
Compensation expense resulting from restricted stock awards to employees, net of cancellation of awards	153,070	—	268	—	—	—	268
Stock-based compensation resulting from stock options granted to non-employees	—	—	160	—	—	—	160
Issuance of restricted stock awards to non-employees and related compensation expenses from outstanding awards	—	—	121	—	—	—	121
Cumulative adjustment upon adoption of EITF06-2 for the Company's sabbatical program	—	—	—	—	—	(272)	(272)
Net loss	—	—	—	—	—	(59,282)	(59,282)
Other comprehensive gain	—	—	—	22	—	—	22
Total comprehensive loss	—	—	—	—	—	—	(59,260)
Balance at December 31, 2007	40,378,413	\$ 40	\$297,239	\$—	\$—	\$(208,765)	\$ 88,514

See accompanying notes.

**Anesiva, Inc.**  
**(a development stage company)**  
**(In thousands)**

**CONSOLIDATED STATEMENTS OF CASH FLOW**

	Year Ended December 31,			Period from
	2007	2006	2005	March 6, 2001 (inception) to December 31, 2007
<b>Operating activities</b>				
Net loss	\$(59,282)	\$(55,567)	\$(33,518)	\$(208,493)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	350	329	543	4,384
Extraordinary gain	—	—	(1,725)	(1,725)
Non-cash stock-based compensation	8,284	11,269	2,857	24,752
Non-cash retention plan	—	—	4,828	4,828
Write down of and realized loss on sales of marketable securities	1,255	—	—	1,255
Interest expense	14	—	—	14
Non-cash interest expense	—	—	—	131
Issuance of common stock for licensing fee	—	—	—	1,536
Acquired in-process research and development	—	—	—	5,716
Amortization of intangible assets	—	—	—	448
Loss (gain) on disposal of equipment	(151)	267	(22)	27
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(513)	313	86	(459)
Inventories	(559)	—	—	(559)
Other assets	(673)	(53)	1,417	(745)
Accounts payable	531	1,802	1,029	3,351
Accrued clinical trial liabilities	1,135	(2,766)	195	(220)
Accrued compensation	24	(296)	694	673
Other accrued liabilities	1,424	81	(1,901)	1,394
Net cash used in operating activities	<u>(48,161)</u>	<u>(44,621)</u>	<u>(25,517)</u>	<u>(163,692)</u>
<b>Investing activities</b>				
Purchases of property and equipment	(7,253)	(8,206)	(59)	(16,622)
Proceeds from disposal of equipment	171	33	18	475
Purchases of marketable securities	(31,800)	(49,503)	(18,548)	(141,343)
Sales of marketable securities	69,168	66,153	47,584	198,085
Acquisition of PowderJect Technologies, Inc.	—	—	—	(1,442)
Other acquisition related expenditures	—	—	—	(97)
Net cash provided by investing activities	<u>30,286</u>	<u>8,477</u>	<u>28,995</u>	<u>39,056</u>
<b>Financing activities</b>				
Repayment of capital lease obligations	—	(150)	—	(193)
Cash acquired	—	—	22,575	22,575
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	—	77,887
Proceeds from issuances of common stock	51,434	43,007	93	94,580
Proceeds from debt	10,827	—	—	20,627
Net cash provided by financing activities	<u>62,261</u>	<u>42,857</u>	<u>22,668</u>	<u>215,476</u>
Net increase in cash and cash equivalents	44,386	6,713	26,146	90,840
Cash and cash equivalents, beginning of period	46,454	39,741	13,595	—
Cash and cash equivalents, end of period	<u>\$ 90,840</u>	<u>\$ 46,454</u>	<u>\$ 39,741</u>	<u>\$ 90,840</u>
<b>Cash flow for merger with AlgoRx</b>				
Marketable securities	—	—	\$ 59,915	\$ 59,915
Restricted cash	—	—	450	450
Other current assets	—	—	1,129	1,129
Accrued compensation	—	—	(1,361)	(1,361)
Other accrued liabilities	—	—	(5,002)	(5,002)
Fair value of options assumed	—	—	(6,539)	(6,539)
Direct transaction costs	—	—	(1,951)	(1,951)
Common stock issued	—	—	(68,852)	(68,852)
<b>Supplemental disclosure of cash flow information</b>				
Cash paid during the year for interest	<u>\$ 257</u>	<u>\$ 6</u>	<u>\$ —</u>	<u>\$ 269</u>
<b>Supplemental cash flow information</b>				
Issuance of \$8,016,000 of convertible preferred stock and \$228,923 of common stock in connection with acquisition of PowderJect Technologies, Inc.	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,245</u>
Conversion of convertible preferred stock to common stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 87,687</u>	<u>\$ 95,703</u>
Conversion of convertible notes to preferred stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 9,800</u>
Equipment acquired under capital leases	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 43</u>

See accompanying notes.

**Anesiva, Inc.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2007**

**1. Summary of Significant Accounting Policies**

***Organization, Description of Business and Basis of Presentation***

Anesiva, Inc. (the "Company" or "Anesiva") was incorporated on January 19, 1999 in Delaware. On December 15, 2005, Anesiva merged with AlgoRx Pharmaceuticals, Inc. ("AlgoRx") by issuing common stock of Anesiva to AlgoRx's stockholders. Immediately following the transaction, approximately 62% of the outstanding fully-diluted shares of Anesiva common stock were owned by AlgoRx's stockholders. Therefore, the acquiring entity for accounting purposes is AlgoRx in Statement of Financial Accounting Standards No. 141 ("SFAS 141"), *Business Combinations*. The historical consolidated financial statements dated before December 15, 2005 are those of AlgoRx and the consolidated statement of operations for the year ended December 31, 2005 comprises the results from operations of AlgoRx from January 1, 2005 through December 15, 2005 and those of Anesiva and AlgoRx from December 16, 2005 through December 31, 2005.

AlgoRx was incorporated on March 6, 2001 in Delaware. During 2003, AlgoRx was headquartered in Cranbury, New Jersey, with facilities also in Fremont, California. In July of 2004, AlgoRx moved its headquarters to Secaucus, New Jersey. AlgoRx was focused on building a diversified portfolio of pharmaceutical products and technologies to address the pain therapeutic market. AlgoRx's activities since inception had consisted principally of acquiring product and technology rights, raising capital, establishing facilities and performing research and development. Accordingly and because AlgoRx is the acquiring entity, the Company is also in the development stage as defined by Statement of Financial Accounting Standards No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company operates in one business segment.

The Company expects to continue to incur substantial losses over the next several years. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical trials. Further, the Company's second product candidate, Adlea™, will require regulatory approval prior to commercialization. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of equity securities, research and development contract revenue, and in the longer term, revenue from product sales of Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, or Zingo.

***Principles of Consolidation***

The consolidated financial statements include the accounts of Anesiva, Inc. and its wholly owned subsidiaries, AlgoRx Pharmaceuticals, Inc., located in Secaucus, New Jersey and Anesiva Hong Kong Limited. Intercompany accounts and transactions have been eliminated.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

***Cash and Cash Equivalents and Marketable Securities***

The Company invests its excess cash in money market funds and in highly liquid debt instruments of the U.S. government, its agencies and municipalities and corporate notes. All highly liquid investments with stated maturities of 90 days or less from date of purchase are classified as cash equivalents; highly liquid investments with stated maturities of greater than 90 days are classified as marketable securities.

**Anesiva, Inc.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The Company determines the appropriate classification of investments in debt securities at the time of purchase. Cash equivalents and marketable securities are classified as available-for-sale securities as the Company does not intend to hold securities with stated maturities greater than twelve months until maturity. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income or expense.

In August 2007, \$2.9 million invested in two AAA-rated auction rate securities failed to settle in auctions. The failures resulted in the interest rate on these investments resetting at higher rates, one-month Libor plus 50 or 125 basis points. The Company concluded that the impairment for both securities was other-than-temporary. At September 30, 2007 the Company had written-down the carrying amount for one investment to \$1.8 million and recognized a loss of \$160,000 in the three months ended September 30, 2007. In November 2007, the Company sold that security for \$1.6 million and realized an additional loss of \$195,000. As of December 31, 2007, the Company has not received an offer from the issuer of the other auction rate security that was carried at \$900,000 prior to its failed auction in August 2007. The Company does not foresee that it will be able to receive any bid in less than six months from the date that instrument auction failed. The Company continues to conclude that the impairment for this security is other-than-temporary and it is maintaining the carrying amount for that investment at \$0. The Company recognized a loss of \$900,000 during the three months ended September 30, 2007. Based on its ability to access its cash and other short-term investments, its expected operating cash flows, and its other sources of cash, the Company does not anticipate the lack of liquidity on this investment will affect its ability to operate its business as usual. At December 31, 2007, this investment continues being rated AAA and is paying interest at December 31, 2007. Should this auction rate security reset or trade again due to improvements in the corporate debt market, the Company would then be able to sell it. The Company has reviewed its commercial paper position at December 31, 2007 for impairment and concluded that its carrying value approximated its fair value.

***Fair Value of Financial Instruments***

The carrying values of the Company's financial instruments, which include cash and cash equivalents, marketable securities, accounts payable and accrued expenses, approximate their fair values.

***Inventories***

Inventories are stated at the lower of cost or market and consist primarily of material and certain contract manufacturing costs for the production of Zingo that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for Zingo. If inventory costs exceed expected market value due to obsolescence, impairment charges may be recorded as deemed necessary by management for the difference between the cost and the market value. There were no impairment charges reserved at December 31, 2007.

***Other Assets***

Other assets consist of nonmarketable equity investments in Lumen Therapeutics LLC, or Lumen, and Particle Therapeutics Ltd., or Particle Therapeutics, carried at the cost of approximately \$89,000 and \$50,000, respectively, which approximate to their fair values.

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***Change in Accounting Principle***

On January 1, 2007, the Company adopted Emerging Issues Task Force (or "EITF") Issue No. 06-2, "Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43, Accounting for Compensated Absences" (or "EITF 06-2"). EITF 06-2 states that if all the conditions of paragraph 6 of FASB 43 are met, compensation costs for sabbatical and other similar benefit arrangements should be accrued over the requisite service period. Paragraph 6 of FASB 43 states that a liability should be accrued for employees' future absences if the following are met: (a) the employer's obligation is attributable to employees' services already rendered; (b) the obligation relates to rights that vest or accumulate; (c) payment of the compensation is probable; and (d) the amount can be reasonably estimated. EITF 06-2 is effective for fiscal years beginning after December 15, 2006. Upon adoption of EITF 06-2, the Company recorded a one-time adjustment of approximately \$272,000 to accumulated deficit as a cumulative effect of a change in accounting principle.

In June 2006, the FASB issued interpretation No. 48, *Accounting for Uncertainty in Income Tax*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, or SFAS No. 109. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transaction. The Company adopted FIN 48 effective January 1, 2007. In accordance with FIN 48, paragraph 19, the Company has decided to classify interest and penalties as a component of tax expense. As a result of the implementation of FIN 48, the Company recorded approximately \$1.3 million unrecognized tax benefit as a reduction to deferred tax assets, all of which is currently offset by a full valuation allowance that had no effect on the beginning balance of accumulated deficit or the net balance sheet.

***Restricted Investments***

Under certain operating lease agreements, the Company is required from time to time to set aside cash as collateral. At December 31, 2007 and 2006, the Company had approximately \$658,000, of which approximately \$68,000 was included in prepaid expenses and other current assets, and \$590,000 of restricted cash related to such agreements, respectively. At December 31, 2006, the Company had approximately \$624,000 of restricted cash related to such agreements.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, which are three years for computer, five years for furniture, laboratory and certain manufacturing equipment and ten years for all other manufacturing equipment, using the straight-line method.

Leasehold improvements are amortized over the lives of the related leases or their estimated useful lives, whichever is shorter, using the straight-line method.

***Long-Lived Assets***

Long-lived assets with definite lives that are held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

amount of the assets, the assets are written down to their estimated fair values. Long-lived assets with definite lives to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

***Revenue Recognition***

The Company's revenue recognition policies are in accordance with Securities and Exchange Commission (SEC) Staff Accounting Bulletin No. 104, or SAB 104, and EITF 00-21, *Revenue Recognition in Financial Statements*, which provides guidance on revenue recognition in financial statements and is based on the interpretations and practices developed by the SEC. SAB 104 requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence exists of an arrangement; (2) delivery has occurred or services have been rendered; (3) the fee is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the fees charged for services rendered and products delivered and the collectibility of those fees. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. If the Company has an ongoing involvement or performance obligation, non-refundable up-front fees are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the consolidated statement of operations over the term of the performance obligation. If the Company has no ongoing involvement or performance obligation, non-refundable up-front fees are generally recorded as revenue in the period in which the rights are transferred.

In November 2006, the Company licensed a proprietary database of clinical trial results in exchange for the equity investment in Lumen and future royalty payments on the sale of Lumen's lead drug candidate. In December 2006, the database was delivered to Lumen. In August 2007, the Company entered into an agreement granting Particle Therapeutics a license to incorporate its drug delivery technology into its needle-free, transdermal delivery system for glucagon, a hormone commonly used for the treatment of hypoglycemia associated with Type 1 and Type 2 diabetes. Under the terms of the license agreement, the Company has received an up-front payment in ordinary shares and will receive milestone payments for certain key clinical and regulatory achievements, royalties on future sales, as well as royalties on revenues from any future sub-licensing of the technology from Particle Therapeutics to third parties. In accordance with Accounting Principles Board ("APB") Opinion 29, *Accounting for Nonmonetary Transactions*, or APB 29, the fair value of the exchanges is based on the fair value of the shares received, or approximately \$89,000 from Lumen and \$50,000 from Particle Therapeutics. For the years ended December 31, 2007 and 2006, the Company recognized \$50,000 and \$89,000 in non monetary revenue, respectively. Under Emerging Issues task Force ("EITF") 00-8: *Accounting by a Grantee for an Equity Instrument to Be Received in Conjunction with Providing Goods or Services*, changes in fair value of the shares received from Lumen and Particle Therapeutics after the measurement date unrelated to the achievement of performance conditions will be accounted for in accordance with any relevant literature on the accounting and reporting for investments in equity instruments.

***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development costs consist of salaries, employee benefits, laboratory supplies, consulting services, manufacturing products and services, preclinical and clinical services, and facility costs.

Acquired in-process research and development relates primarily to in-licensed technology, intellectual property and know-how. The Company evaluates the stage of development of acquired projects, taking into account the level of effort, time and estimated cost associated with further developing the in-process technology and producing a commercial product. The nature of the remaining efforts for completion of acquired in-process

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research and development projects generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, and ongoing feedback from regulatory authorities, including obtaining marketing approval. In addition, acquired products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost to produce these products in a commercial setting, changes in the reimbursement environment, or the introduction of new competitive products. As a result of the uncertainties noted above, the Company expenses such acquired in-process research and development projects when incurred.

***Concentration of Credit Risk***

The Company's financial instruments that are exposed to credit risks consist primarily of cash and cash equivalents and marketable securities. The Company maintains its cash and cash equivalents in bank accounts, which, at times, exceed federally insured limits. Marketable securities are held in custody by a large bank, and the Company does not require collateral to support such instruments. For the year ended December 31, 2007, the Company has experienced \$1.3 million losses in such accounts. At December 31, 2007, the Company did not hold any marketable securities and it believes it is not exposed to significant credit risk related to cash and cash equivalents.

***Income Taxes***

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

***Comprehensive Gain and Loss***

The Company's other comprehensive losses or gains for the years ended December 31, 2007, 2006 and 2005 were approximately \$22,000 in gains, \$79,000 in gains and \$51,000 in losses, respectively, and are attributed to net unrealized losses or gains on marketable securities. The Company reports comprehensive loss in accordance with Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income* ("SFAS 130").

***Net Loss Per Share***

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards No. 128, *Earnings per Share* ("SFAS 128"). Under the provisions of SFAS 128, basic net loss per common share ("Basic EPS") is computed by dividing net loss by the weighted-average number of common shares outstanding (excluding unvested founders' shares subject to repurchase). Diluted net loss per common share ("Diluted EPS") is computed by dividing net loss by the weighted-average number of common shares and dilutive common shares equivalents then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, convertible debt, shares issuable upon the exercise of stock options, and unvested founders' shares subject to repurchase. Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Pursuant to the terms of the merger agreement, which were approved by Anesiva and AlgoRx stockholders on December 15, 2005, and due to the liquidation preference of AlgoRx's preferred stockholders, none of AlgoRx's common stockholders received shares of common stock of Anesiva in the transaction. Shares of common stock presented in loss per share calculations herein are the historical AlgoRx common shares up to December 14, 2005 included, and the historical Anesiva common shares from December 15, 2005 and after. None of the shares of AlgoRx's common stock were converted into the shares of Anesiva's common stock. All AlgoRx common shares were cancelled on December 15, 2005.

***Stock-Based Compensation***

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases pursuant to the Employee Stock Purchase Plan based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107, or SAB 107, relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

Prior to the adoption of SFAS 123(R), the Company accounted for employee stock options using the intrinsic value method in accordance with APB 25 Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB 25, and related interpretations and have adopted the disclosure-only provisions of SFAS 123, as amended by SFAS 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—An Amendment of FASB Statement No. 123*.

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. The consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

In November 2005, the Financial Accounting Standards Board, or FASB, issued FSP No. 123R-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*. The Company has adopted the simplified method to calculate the beginning balance of the additional paid-in-capital, or APIC, pool of the excess tax benefit, and to determine the subsequent impact on the APIC pool and the consolidated statements of cash flows for the tax effects of employee stock-based compensation awards that were outstanding upon adoption of SFAS 123(R).

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company values share-based awards using the Black-Scholes option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the consolidated statement of operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in the consolidated statement of operations, other than as related to

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options granted to employees and directors at an exercise price deemed lower than the fair value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during that period. Stock-based compensation expense recognized in the Company's consolidated statement of operations for the years ended December 31, 2007 and 2006 includes compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). The Company uses the straight-line single option method to allocate stock-based compensation expense. As stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, stock compensation has been reduced for estimated stock option forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

Stock-based compensation expense recognized under SFAS 123(R) for the year ended December 31, 2007 was \$8.0 million, which consisted of stock-based compensation expense related to employee stock options, employee restricted stock awards and employee stock purchases of \$7.5 million, \$268,000 and \$149,000, respectively. Stock-based compensation expense recognized under SFAS 123(R) for the year ended December 31, 2006 was \$11.1 million, which consisted of stock-based compensation expense related to employee stock options, restricted stock awards and employee stock purchases of \$10.8 million, \$150,000 and \$140,000, respectively. Stock-based compensation expense related to employee stock options recognized under APB 25 during the year ended December 31, 2005 was \$2.7 million.

On January 1, 2006, the Company reversed \$572,000 related to unamortized deferred stock compensation from options granted below its stock deemed fair value before December 31, 2005 and restricted stock awards as a result of its adoption of SFAS 123(R).

The Company has also granted restricted stock awards to consultants. The Company accounts for stock awards issued to such non-employees in accordance with the provisions of Emerging Issues Task Force, or EITF, Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or Issue No. 96-18. Under Issue No. 96-18, stock awards to non-employees are accounted for at their respective fair values using the Black-Scholes option-pricing model unless a more readily determinable fair value is available. The fair value of options granted to non-employees is remeasured during the performance period as the underlying options vest or as milestones are reached. During the year ended December 31, 2007, the Company granted 7,000 shares of restricted stock and 17,000 shares of stock options to non-employees and recorded \$160,000 and \$121,000 in stock-based compensation expenses, respectively. During the year ended December 31, 2006, the Company granted 24,500 shares of restricted stock and 20,000 shares of stock options to non-employees and recorded \$129,000 and \$63,000 in stock-based compensation expense, respectively.

*Employee Stock Plans*

The 1999 Equity Incentive Plan was adopted in July 1999 and provides for the issuance of stock options. The Anesiva Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the

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reservation of an additional 250,000 shares of common stock for issuance under the 1999 Equity Incentive Plan and to rename it the 2003 Equity Incentive Plan (the "2003 Plan"), to become effective upon the effective date of the registration statement. Shares reserved under the 2003 Plan are increased annually for the life of the 2003 Plan on January 1 beginning in 2006, by the lesser of (a) 5% of the number of shares of common stock outstanding on such date and (b) 2,500,000 shares of common stock. However, the board of directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on such date.

Stock options granted under the 2003 Plan may be either incentive stock options, nonstatutory stock options, stock bonuses, or rights to acquire restricted stock. Incentive stock options may be granted to employees with exercise prices of no less than the fair value of the common stock on the grant date and nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 50% of the fair value of the common stock on the grant date, as determined by the board of directors. If, at the time the Company grants an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of its stock, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the board of directors. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated. Stock options granted under the 2003 Plan have vesting terms as determined by the board of directors.

The Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the 2003 Nonemployee Directors' Stock Option Plan (the "Directors' Plan"). The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to non-employee directors. Shares reserved under the plan are increased annually on January 1, from 2006 until 2014, by the number of shares of common stock subject to options granted during the prior calendar year. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased. Stock options granted under the Directors' Plan vest as follows: initial grants vest in 48 equal monthly installments from the date of grant; and annual grants vest in 12 equal monthly installments from the date of grant.

Pursuant to the merger agreement between the Company and AlgoRx, all stock options to purchase shares of common stock of AlgoRx were canceled. All the information presented in this Note reflects the Company's historical equity incentive plans and not those of AlgoRx.

Common stock options may include a provision whereby the holder, while an employee, director, or consultant, may elect at any time to exercise the option as to any part or all of the shares subject to the option prior to the full vesting of the option. Any unvested shares so purchased are subject to its repurchase at a price equal to the original purchase price of the stock. This right of repurchase will lapse with respect to option shares upon vesting of the underlying options. Stock options granted under the Directors' Plan vest as follows: initial grants vest in 48 equal monthly installments from the date of grant; and annual grants vest in 12 equal monthly installments from the date of grant. Stock options granted under the 2003 Plan have vesting terms as determined by the board of directors.

*Adoption of SFAS 123(R)*

Employee stock-based compensation expense recognized in 2006 and 2007 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to

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be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates the fair value of each option grant on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions, which was applied to AlgoRx's options for the year ended December 31, 2005:

Risk-free interest rate .....	4.2%
Expected life (in years) .....	9.0
Volatility .....	120%
Dividend yield .....	—
Fair value of options granted .....	\$6.34

The fair values of stock options granted to employees of Anesiva for the years ended December 31, 2005, 2006 and 2007 were estimated on the respective dates of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2007	2006	2005
Risk-free interest rate .....	4.7%	5.0%	4.1%
Expected life (in years) .....	5.4	4.8	4.0
Volatility .....	78%	89%	107%
Dividend yield .....	—	—	—
Fair value of options granted .....	\$4.87	\$4.97	\$10.74

The Company estimates the future volatility of its common stock to be the measure of the daily volatility of its common stock from February 12, 2004 (the date of the Company's initial public offering of common stock) through the end of respective periods in the above table. The expected life of an award is based on historical experience and on the terms and conditions of the stock awards granted to employees.

The following table summarizes the non-cash stock compensation charges under SFAS 123(R) in the year ended December 31, 2007 and 2006 (in thousands):

	Stock options		ESPP		Restricted Stock	
	2007	2006	2007	2006	2007	2006
Research and development .....	\$1,761	\$ 3,533	\$ 78	\$ 86	\$ 85	\$ 58
General and administrative .....	5,825	7,254	71	64	183	82
Total .....	<u>\$7,586</u>	<u>\$10,787</u>	<u>\$149</u>	<u>\$150</u>	<u>\$268</u>	<u>\$140</u>

At December 31, 2007, the unrecognized compensation expense related to unvested outstanding stock options is approximately \$10.1 million which will be recognized through 2011, the weighted average remaining recognition period is approximately 2.35 years and the aggregate intrinsic value of exercisable options is approximately \$23,000. At December 31, 2006, the unrecognized compensation expense related to unvested outstanding stock options is approximately \$13.0 million which will be recognized through 2010, the weighted average remaining recognition period is approximately 1.31 years and the aggregate intrinsic value of exercisable options is approximately \$217,000.

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*Pro Forma Information under SFAS 123*

The following table illustrates the effect on net loss and net loss per common share had the Company applied in the year ended December 31, 2005, the fair value provisions of SFAS 123 to employee stock compensation (in thousands, except per share numbers):

Net loss, as reported .....	\$(33,518)
Add: Stock-based employee compensation expense, included in reported net loss .....	2,220
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards .....	<u>(2,724)</u>
Pro forma net loss under fair value method for all awards .....	<u>\$(34,022)</u>
Net loss per share (basic and diluted):	
As reported .....	<u>\$ (16.89)</u>
Pro forma .....	<u>\$ (17.14)</u>

***Recent Accounting Pronouncements***

In September 2006, the Financial Accounting Standards Board, or FASB issued SFAS No. 157, *Fair Value Measurement*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is evaluating the impact of adopting SFAS No. 157 on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 allows entities to voluntarily choose, at specified election dates, to measure many financial assets and financial liabilities (as well as certain non-financial instruments that are similar to financial instruments) at fair value, or the fair value option. The election is made on an instrument-by-instrument basis and is irrevocable. If the fair value option is elected for an instrument, SFAS No. 159 specifies that all subsequent changes in fair value for that instrument shall be reported in earnings. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company is currently evaluating the effect that SFAS No. 159 will have on its consolidated financial statements, should it decide to adopt its provisions.

In June 2007, the FASB ratified EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact of the pending adoption of EITF 07-3 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*. SFAS No. 160 changes the way the consolidated income statement is presented. It requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. This statement also requires expanded disclosures in the consolidated financial statements that clearly identify and distinguish between the interests of the parent's owners

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and the interests of the noncontrolling owners of a subsidiary. Those expanded disclosures include a reconciliation of the beginning and ending balances of the equity attributable to the parent and the noncontrolling owners and a schedule showing the effects of changes in a parent's ownership interest in a subsidiary on the equity attributable to the parent. SFAS No. 160 is effective as of the beginning of an entity's first fiscal year that begins after December 15, 2008. The Company is currently evaluating the effect that SFAS No. 160 will have on its consolidated financial statements.

**2. Acquisitions**

***AlgoRx Pharmaceuticals, Inc.***

On December 15, 2005, the Company completed the merger with AlgoRx. The Company issued 13,047,716 shares of its common stock in exchange for all of AlgoRx's outstanding shares of Series A preferred stock, Series B preferred stock, Series C preferred stock, common stock and warrant to purchase Series C preferred stock. Because AlgoRx stockholders owned approximately 62% of the fully-diluted shares of the combined company immediately following the consummation of the merger, AlgoRx was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition under the purchase method of accounting for business combinations in accordance with accounting principles generally accepted in the United States.

As of December 15, 2005, the Company had 7,025,772 shares of common stock outstanding. Based on market closing price of December 15, 2005, the fair value of the Company's outstanding shares was \$9.80 per share or approximately \$68.8 million. The total purchase price of \$77.3 million included the fair value of the Company's common stock of approximately \$68.8 million, the fair value of the Company's outstanding stock options of approximately \$6.5 million and direct transaction costs of approximately \$2.0 million.

The merger was completed to provide the Company with the ability to create a late-stage company with four products in the combined pipeline.

The total purchase price of the merger was as follows (in thousands):

Anesiva common stock .....	\$68,852
Fair value of options assumed .....	6,539
Direct transaction costs .....	<u>1,951</u>
Total purchase price .....	<u>\$77,342</u>

The unaudited condensed balance sheet of Anesiva at December 15, 2005 is as follows (in thousands):

Cash, cash equivalent and marketable securities .....	\$82,490
Prepaid expenses and other assets .....	<u>1,129</u>
Total current assets .....	83,619
Property and equipment, net .....	2,495
Other assets .....	<u>450</u>
Total assets .....	<u>\$86,564</u>
Total current liabilities .....	<u>\$(5,002)</u>
Net tangible assets .....	<u>\$81,562</u>

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Approximately \$383,000 in accrued restructuring costs, which consist of severance and benefit costs, included in Anesiva's current liabilities at December 15, 2005 were assumed by the Company.

Under the purchase method of accounting, the total purchase price as shown in the table above was allocated to the Company's net tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of December 15, 2005. The allocation of the purchase price associated with certain assets was as follows (in thousands):

Net tangible assets .....	\$81,562
In process technology—NF-KB Decoy .....	2,710
Assembled workforce .....	1,610
Negative goodwill .....	<u>(8,540)</u>
Total preliminary estimated purchase price .....	<u>\$77,342</u>

In accordance with APB No. 30, any excess of fair value of acquired net assets over purchase price (negative goodwill) is recognized as an extraordinary gain in the period the business combination is completed. The excess is allocated as a pro rata reduction of the amounts that otherwise are assigned to the non-current acquired assets. Any excess remaining after reducing to zero the amounts that otherwise would have been assigned to those assets is recognized as an extraordinary gain.

The pro rata reduction of non-current tangible and intangible assets acquired was as follows (in thousands):

Negative goodwill .....	\$(8,540)
In-process technology— NF-KB Decoy .....	2,710
Assembled workforce .....	1,610
Property and equipment, net .....	<u>2,495</u>
Excess negative goodwill—Extraordinary gain .....	<u>\$(1,725)</u>

The extraordinary gain per weighted average share of 1,984,951 for the year ended December 31, 2005 is \$0.87 per share.

The following unaudited pro forma information presents a summary of consolidated results of operations as if the merger had taken place at the beginning of 2005 (in thousands, except per share information):

	<u>As of December 31, 2005</u>
	(unaudited)
Total revenues .....	\$ 20,342
Net loss .....	\$(66,723)
Pro forma basic and diluted earnings per share .....	\$ (3.44)

The pro forma net loss per share for 2005 exclude the excess negative goodwill noted above. The pro forma information is not necessarily indicative of results that would have occurred had the acquisition been in effect for the periods presented or indicative of results that may be achieved in the future.

***Retention Bonus Plan***

In July 2005, AlgoRx adopted the AlgoRx 2005 Retention Bonus Plan, or Retention Bonus Plan, pursuant to which AlgoRx's 22 employees and one director became entitled to receive a retention bonus if they remain employed

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by AlgoRx or continue to provide services through the effective time of the merger or are terminated without cause within 90 days prior to the merger. The bonus payment pursuant to the Retention Bonus Plan consisted of a fixed and a discretionary bonus of 4.33% and 2.17%, respectively, of the total value of Anesiva shares issued to AlgoRx stockholders in the merger transaction. The AlgoRx board of directors has determined that up to 40% of the retention bonus payment may be paid in cash, and the remaining 60% of the retention bonus payment may be paid in Anesiva common stock. On December 16, 2005, the fixed and discretionary bonus pool paid was approximately \$8.0 million, consisting of 511,410 shares of Anesiva common stock, of which 41,528 shares were held in escrow until June 15, 2006, and approximately \$3.2 million in cash. The average of the closing sale prices for Anesiva common stock for the five day consecutive trading days ending three trading days prior to the merger closing date, or \$9.44 per share, was used for purposes of determining the number of shares to issue as prescribed under the Retention Bonus Plan.

Under the Retention Bonus Plan, one director received 13,258 shares of Anesiva common stock, of which 1,076 shares were held in escrow until June 15, 2006, and \$83,440 in cash.

**3. Restructurings**

In December 2005, the Company announced a restructuring plan to reduce research costs, realign development efforts and realize operational efficiencies in general and administrative functions. The Company recorded a charge of \$439,000 in severance salaries and other termination-related benefits related to the termination of 19 employees, which was included in accrued compensation on the balance sheet at December 31, 2005. During the year ended December 31, 2006, the Company recorded a charge of \$881,000 to reflect the accrual of severance salaries and benefits for employees related to the termination of ten employees.

In October 2006, the Company announced the closure of an office space in Secaucus, New Jersey. This restructuring was done in order to further reduce its ongoing operational costs. As a result of this restructuring, the Company incurred approximately \$176,000 in severance salaries and other benefits related to the termination of five employees.

During the years ended December 31, 2007 and 2006, the Company paid severance and other benefits related to the restructuring plan. The following table sets forth the activity in the restructuring reserve related to employee severance (in thousands):

	<u>Employee Severance Costs</u>
Restructuring reserve at December 31, 2005 .....	\$ 439
Accrual for salaries and termination-related benefits .....	1,067
Payment against reserve .....	<u>(1,329)</u>
Restructuring reserve at December 31, 2006 .....	\$ 167
Payment against reserve .....	<u>(167)</u>
Restructuring reserve at December 31, 2007 .....	<u>\$ —</u>

In addition to employee severance costs, the Company incurred a \$24,000 charge in the year ended December 31, 2006 related to exiting the lease of its laboratory and office space in Sunnyvale, California in March 2006. The lease related to this space expires on March 31, 2008. At December 31, 2007, the remaining accrued liability related to this sublease of the Sunnyvale office was \$3,000.

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Due to the closure of an office space in Secaucus, New Jersey, the Company also incurred approximately a \$487,000 charge, net of \$817,000 in estimated future sublease income, in the year ended December 31, 2006, related to exiting the lease of its office space in Secaucus, New Jersey and other office equipment operating leases. The lease related to this office space expires on July 31, 2009 and the leases related to office equipment expired and will expire on June 2007, March 2008, and January 2009. During the year ended December 31, 2007, the Company paid \$365,000 related to accrued liability for exiting the lease of its office space in Secaucus, New Jersey and other related equipment operating leases. During the year ended December 31, 2007, the Company has increased the total estimated liability for exiting its office space in Secaucus, New Jersey by \$579,000, or \$0.02 per weighted average shares of common stock for the year ended December 31, 2007, due to a change in estimated future sublease income to \$0, which is the result of a worsening of the office rental market in Secaucus, New Jersey as observed in the third quarter of 2007. This change in estimate was based on consultation with real estate professional in this market the lack of interest by prospective sublessors and a marked increase of vacancy rate of space in the building the Company occupies and the immediate vicinity. The following table sets forth the activity in the accrued liability related to exiting the lease of its office space in Secaucus, New Jersey, which is included in other accrued liabilities and other long term liabilities at December 31, 2007 (in thousands):

	<u>Exit Costs of Secaucus Office</u>
Accrued liabilities at December 31, 2006 .....	\$ 443
Additional accrual for exit costs of Secaucus office recorded in September 2007 .....	579
Payment against accrued liability .....	<u>(365)</u>
Accrued liabilities at December 31, 2007 .....	<u>\$ 657</u>

**4. Available-for-Sale Investments**

The following is a summary of available-for-sale investments as of December 31, 2007 (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized (Loss)/Gain</u>	<u>Fair Value</u>
Maturities within one year:			
Commercial paper .....	\$3,690	\$—	\$3,690
Total .....	<u>\$3,690</u>	<u>\$—</u>	<u>\$3,690</u>
Reported as:			
Cash and cash equivalents .....	3,690	—	3,690
Total .....	<u>\$3,690</u>	<u>\$—</u>	<u>\$3,690</u>

At December 31, 2007, the Company holds one AAA rated security that was purchased for \$900,000 and was written down to \$0 in the third quarter of 2007 due to the lack of liquidity for this security. For the year ended December 31, 2007, the Company realized a \$355,000 loss on the sale of one corporate debt obligation security.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following is a summary of available-for-sale investments as of December 31, 2006 (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
<b>Maturities within one year:</b>			
Certificate of deposit .....	\$ 1,000	\$—	\$ 1,000
Commercial paper .....	27,235	(21)	27,214
Corporate debentures .....	2,002	(1)	2,001
State and municipal debenture .....	<u>36,600</u>	<u>—</u>	<u>36,600</u>
<b>Total .....</b>	<b><u>\$66,837</u></b>	<b><u>\$(22)</u></b>	<b><u>\$66,815</u></b>
<b>Reported as:</b>			
Cash and cash equivalents .....	28,235	(21)	28,214
Marketable securities .....	<u>38,602</u>	<u>(1)</u>	<u>38,601</u>
<b>Total .....</b>	<b><u>\$66,837</u></b>	<b><u>\$(22)</u></b>	<b><u>\$66,815</u></b>

**5. Inventories**

Inventories consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Raw material .....	\$274	\$—
Work in process .....	285	—
<b>Total .....</b>	<b><u>\$559</u></b>	<b><u>\$—</u></b>

**6. Property and Equipment**

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

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Leasehold improvements .....	\$ 274	\$ 9
Computer and office equipment .....	783	217
Laboratory equipment .....	1,204	1,508
Construction-in-process .....	7,408	7,555
Manufacturing equipment .....	<u>6,662</u>	<u>349</u>
	16,331	9,638
Less accumulated depreciation and amortization .....	<u>(1,055)</u>	<u>(1,192)</u>
<b>Property and equipment, net .....</b>	<b><u>\$15,276</u></b>	<b><u>\$ 8,446</u></b>

Depreciation and amortization expense was approximately \$350,000, \$329,000, \$543,000, and \$4,384,000 for the years ended December 31, 2007, 2006, 2005 and for the period from March 6, 2001 (inception) to December 31, 2007, respectively. The Company recorded a gain on disposal of equipment of approximately \$22,000 and \$151,000 during the year ended December 31, 2005 and 2007 respectively. For

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

the year ended December 31, 2006, the Company disposed certain computer and laboratory equipment due to the closure of its Sunnyvale, California and Secaucus, New Jersey offices and recorded a recognized loss on disposal of approximately \$267,000.

**7. Other Accrued Liabilities**

Other accrued liabilities consist of the following (in thousands):

	December 31,	
	2007	2006
Accrued legal .....	179	71
Other accrued liabilities .....	2,750	1,560
Total .....	\$2,929	\$1,631

**8. Leases and Commitments**

*Leases*

The Company entered into a lease agreement in May 2004 for office space in Secaucus, New Jersey under a noncancelable operating lease through July 2009. In January 2005, the Company entered into an agreement to increase the amount of rented office space in New Jersey and the lease was extended to 2009. The Company also entered into a new lease for new office space in Sunnyvale, California, which it extended to March 2008. In December 2005, the Company also assumed a lease agreement for office and laboratory space in South San Francisco, California, which expires in June 2007 and a lease agreement for office space in West Conshohocken, Pennsylvania which expires in June 2009. In February 2007, the Company entered into an agreement to increase the amount of rented office space for the expansion of its sales force in West Conshohocken, Pennsylvania. The future minimum payments for all noncancelable operating leases as of December 31, 2007 are as follows (in thousands):

Year ending December 31,	
2008 .....	\$2,326
2009 .....	2,202
2010 .....	1,605
Total .....	\$6,133

Rent expense under operating leases was approximately \$2,548,000, \$2,710,000, \$583,000 and \$7,970,000, for the years ended December 31, 2007, 2006 and 2005 and for the period from March 6, 2001 (inception) to December 31, 2007, respectively.

The Company issued three letters of credit, one for approximately \$450,000 to secure the lease in South San Francisco, California, one for approximately \$140,000 to secure the lease in Secaucus, New Jersey, and one for approximately \$68,000 to secure the lease in West Conshohocken, Pennsylvania. These letters of credit are secured by the Company's cash and as such are reflected in restricted cash and prepaid and other current assets in the accompanying consolidated balance sheets.

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***Equipment Loan Agreement***

In February 2003, the Company entered in a Loan Agreement with a lender for an equipment loan. Pursuant to the Loan Agreement, the Company may receive loan proceeds up to an aggregate of \$1.5 million. The Company had drawn down approximately \$1.4 million of the loan through the year ended December 31, 2003 and did not finance any equipment through the year ended December 31, 2006. The loan carried interest at 8.25% per annum and was repayable in 36 monthly installments through 2006. At September 30, 2006, the Company paid off all principal and interest payments on the equipment line of credit and has no available funds on this equipment line of credit.

In August 2007, the Company entered into an equipment loan and security agreement with General Electric Capital Corporation, GECC, with respect to the financing of laboratory and manufacturing equipment in an amount up to \$15.0 million. The Company borrowed approximately \$6.6 million and \$4.4 million under the agreement on August 30, 2007 and November 30, 2007, respectively, and paid approximately \$152,000 in loan origination fees which are accounted as debt discount and amortized over the life of the loans using the interest rate method. The Company may borrow against qualified purchases of eligible equipment expected through May 31, 2008. Each borrowing will be evidenced by a promissory note and will be solely secured by the financed equipment. The promissory notes for the two borrowings are repayable over 42 months and bear a fixed interest rate of 9.91% per annum. The first six payments under the promissory notes are interest payments and the next 36 payments are both interest and principal payments. The loan and security agreement contains certain restrictive covenants relating primarily to the financed equipment and additional indebtedness. The loan and security agreement also contains provisions permitting the lender to accelerate the loan if the Company is in default. A default includes a failure to pay any amount due under the debt documents which is not cured, a breach of any other obligations under the debt documents which is not cured, and an event or development which could reasonably be expected to have a material adverse effect on it.

***Licenses and Related Party***

In August 2001, the Company entered into an agreement with James N. Campbell, M.D., Richard A. Meyer, M.S. and Marco Pappagallo, M.D. to acquire the exclusive, worldwide license to U.S. Patent Application No. 09/041294 (U.S. Patent No. 5,962,532) and all applications and products relating thereto directed to methods and kits for relieving pain using capsaicin as an anesthetic. The technology licensed under the agreement relates to the steps of administering capsaicin for pain reduction that the Company uses in its product Adlea. This license excludes topical application to the skin of capsaicin and analogues. Upon execution of the agreement, the licensees were paid an aggregate up-front license fee of approximately \$42,000, granted options for an aggregate of 21,667 shares of common stock of AlgoRx Pharmaceuticals, Inc. and reimbursed for expenses associated with filing, prosecution and maintenance of the patent. Upon its merger with AlgoRx, these stock options were terminated. The Company is obligated to pay Drs. Campbell and Pappagallo and Mr. Meyer royalties on any future sales of Adlea by us and any of its sublicensees. The Company is also obligated to pay up to \$775,000 in milestone payments under the agreement, of which, as of December 31, 2007, the Company has paid an aggregate of \$200,000. Of the remaining milestone payments, the Company is obligated to pay \$25,000 upon the grant of a Japanese patent using the licensed technology, \$200,000 upon the first administration of licensed technology in a Phase 3 clinical trial and \$350,000 upon approval of the licensed technology for commercial use by the FDA. The license terminates on March 12, 2018, the date of expiration of the patent (U.S. Patent No. 5,962,532), or earlier upon the date of the invalidation of the patent. The Company's rights under this agreement can be terminated on 10 days' written notice if the Company fails to fulfill any material obligation under the agreement and the failure is not cured by us within 180 days of receiving notice of such failure. The Company can terminate the agreement upon 30 days' prior notice for any reason or upon 10 days prior notice for the failure of any counterparty to fulfill a material obligation not cured within 90 days of its giving notice of the failure. The license is subject to a license granted by Drs. Campbell and Pappagallo and Mr. Meyer to Johns Hopkins University for

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non-profit purposes. The license is subject to a sublicense to the inventors for research and development, with no right to commercialization. Dr. Campbell has been a member of the Board of the Company since June 29, 2007 and received approximately \$105,000 in stock compensation and \$12,000 in cash compensation for 2007, of which approximately \$10,000 was accrued at December 31, 2007.

In March 2002, the Company acquired from then PowderJect Research Limited and now PowderMed Limited, a wholly-owned subsidiary of Pfizer, Inc., a license to intellectual property consisting of over 150 patents and applications relating to the methods and apparatus for the delivery of powder forms of medications. The technology licensed under this agreement with PowderJect includes the technology underlying its product Zingo. The license is exclusive worldwide with respect to products delivered by powder injection into the space between cells under the skin, except for certain immune products and certain products defined as "cytokine drugs" and except for products to which PowderJect retains the exclusive right for delivery in dental procedures to the extracellular space within the oral cavity. With respect to Zingo, the Company is required to pay royalties to PowderMed Limited on any future direct sales and any future sales effected by any sublicense. For products other than Zingo resulting from the licensed technology, the Company is also obligated to pay PowderMed Limited royalties on any future direct sales. The Company must also pay royalties on licensing fees, milestone payments, royalty payments, transfer price and other consideration that the Company receives from any sublicensees, if any.

The term of the license commenced on March 22, 2002 and continues until the expiration of the last patent to expire licensed under the agreement unless the agreement is otherwise terminated. The primary patents licensed under the agreement and used by us in connection with Zingo expire in 2014. The agreement can be terminated by either party if the other party ceases to do business in the ordinary course, or assigns all or substantially all of its assets for the benefit of creditors. Either party can also terminate for material breach if not cured within 60 days of notice or if not cured within 30 days of notice if the breach relates to payment provisions. The license agreement also implemented an intellectual property sharing arrangement pursuant to which the Company and PowderMed Limited are obligated to share with one another any improvements and modifications to the licensed technology made on or before March 22, 2007.

In October 2004, the Company licensed the intellectual property underlying 1207 from Bridge Pharma, Inc. In consideration for the license, the Company paid Bridge Pharma, Inc. an up-front license fee consisting of a cash payment of \$1.0 million and the issuance of 160,000 shares of its common stock. Such amounts were expensed during the fourth quarter of 2004. The Company valued the 160,000 shares at approximately \$1.5 million based on the Company's determination of the fair value of the common stock at the time of issuance. The Company has paid Bridge Pharma \$200,000 for the commencement of Phase 1 trials in October 2006. The Company terminated the license in September 2007.

As of December 31, 2007, the Company could be required to pay up to a total of approximately \$1.0 million in payments for milestones such as the initiation of clinical trials and the granting of patents under all license agreements. As of December 31, 2007, the Company incurred approximately \$2.9 million of milestone charges, including approximately \$1.4 million of cash payments and approximately \$1.5 million of stock compensation, for the execution of agreements, patent approvals and the initiation of U.S. clinical trials. Milestone payments will also be due upon the first administration to a subject using licensed technology in a Phase 1 clinical trial, the first administration to a subject using licensed technology in a Phase 3 clinical trial and FDA approval of Adlea. Phase 3 clinical trials and product approval of Adlea in addition to sales milestones and royalties payable on commercial sales if any occur.

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**9. Joint Venture and Distribution and Marketing Agreement**

***Cooperative Joint Venture Contract with Jiangsu Wanbang Biological Pharmaceutical Corporation Limited***

In October 2007, the Company entered into a Cooperative Joint Venture Contract with Jiangsu Wanbang Biological Pharmaceutical Corporation Limited, a subsidiary of Fosun Pharmaceuticals (Group) Corporation, and Yat Ming Lau, a citizen of Hong Kong, for the establishment of Wanbang Anesiva (Jiangsu) Pharmaceutical Co., Ltd, the Joint Venture. The Company will own 49% of the Joint Venture. The Company will provide to the Joint Venture components for Zingo. The Joint Venture will assemble the components in China and provide Zingo to us for sales in the United States. The Company will make a capital contribution to the Joint Venture and will pay the Joint Venture for assembling Zingo units. The agreement became effective upon approval by the Chinese commerce government authorities in January 2008.

***Co-Promotion and Distribution Agreement with Sagent***

In October 2007, the Company entered into a co-promotion and distribution agreement with Sagent Pharmaceuticals, Inc. related to Zingo. Under the agreement, Sagent will undertake certain promotional activities with respect to Zingo in the United States for a period of three years. These activities will include serving as the key selling contact for hospital pharmacists, the facilitation of Zingo-related contract negotiations with hospitals and group purchasing organizations, and the management of the warehousing and distribution of Zingo. The Company paid Sagent \$500,000 due at signing that is creditable against future royalties and will pay royalties on net sales of Zingo to hospitals and related markets during an agreed-upon time period, which may extend beyond the three year term of the agreement. In addition, the Company will reimburse Sagent for certain direct expenses. Under the agreement, the Company may designate additional marketing partners to address non-hospital markets.

***Exclusive Zingo Marketing and Distribution Agreement with Medical Futures***

In December 2007, the Company entered into an agreement with Medical Futures Inc. whereby the Company granted an exclusive license to Medical Futures for the marketing and distribution of Zingo in Canada. Under the terms of the agreement, Medical Futures will be responsible for all regulatory filings, marketing, distribution and selling in Canada. Upon regulatory approval in Canada, Medical Futures will purchase Zingo at a transfer price. The Company received a \$50,000 upfront payment which is classified as deferred revenue and recognized over the term of the agreement. For the year ended December 31, 2007, the Company recognized approximately \$1,000 in revenue.

**10. Capital Structure**

***Common Stock***

As of December 31, 2007, the Company is authorized to issue 100,000,000 shares of common stock. In October 2005, the Company's Board of Directors approved a proposed amendment to the certificate of incorporation to effect a one-for-four reverse stock split which was approved by a vote of the Company's stockholders in December 2005 and effected on December 15, 2005 in connection with the merger. As the historical financial statements prior to the consummation of the merger and the reverse split reflect the capital structure of AlgoRx, issued and outstanding common stock and options have not been retroactively adjusted to reflect the reverse stock split, except where specifically noted.

Dividends on common stock will be paid when, and if, declared by the Board of Directors. Each holder of common stock is entitled to vote on all matters and is entitled to one vote for each share held.

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In February 2005, the Company issued 19,684 shares of restricted common stock to employees and two directors, half of which will cliff vest on the anniversary dates of the grant date over a two-year period. The weighted-average fair value of this stock at the time of issuance was \$24.72 per share. In 2007, the Company issued 127,650 shares of restricted common stock to employees, one-third of which will cliff vest on the anniversary dates of the grant date over a three-year period. The weighted-average fair value of this stock at the time of issuance was \$7.60 per share. Restricted stock awards are grants that entitle the holder to shares of common stock as the award vests. As a result of these awards, at December 31, 2007, the Company recognized approximately \$268,000 in compensation expense. These stock awards offer employees the opportunity to earn shares of its stock over time, rather than options that give the employee the right to purchase stock at a set price. If all the remaining restricted stock awards that were granted in 2005 and 2007 continue to vest, the Company expects to recognize approximately \$318,000, \$315,000, and \$48,000 in compensation expense during the years ended December 31, 2008, 2009, and 2010 respectively. However, no compensation expense will be recognized for stock awards that do not vest. The shares of restricted stock awards released to employees in the years ended December 31, 2007, 2006 and 2005 were 26,811, 9,375 and 21,373 respectively.

The Company has also granted restricted stock awards and stock options to consultants. The Company accounts for stock awards issued to such non-employees in accordance with the provisions of Emerging Issues Task Force, or EITF, Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or Issue No. 96-18. Under Issue No. 96-18, stock awards to non-employees are accounted for at their respective fair values using the Black-Scholes option-pricing model unless a more readily determinable fair value is available. The fair value of options granted to non-employees is remeasured during the performance period as the underlying options vest or as milestones are reached. During the year ended December 31, 2006, the Company granted 24,500 shares of restricted stock to three consultants with vesting periods ranging from 110 days to one year and recorded \$129,000 in stock-based compensation expense. At December 31, 2006, 22,000 and 2,500 shares of restricted stock were unvested and vested, respectively. During the year ended December 31, 2007, the Company granted 7,000 shares of restricted stock to two non-employees with vesting periods of 157 days to one year and recorded \$121,000 in stock-based compensation expense.

***Preferred Stock***

As of December 31, 2007, the Company was authorized to issue 5,000,000 shares of preferred stock.

***Convertible Preferred Stock***

As of December 31, 2004, AlgoRx was authorized to issue 137,405,754 shares of preferred stock. In April 2001, AlgoRx issued 9,150,000 shares of Series A convertible preferred stock ("Series A"). In March 2002, AlgoRx issued 17,858,462 shares of Series B convertible preferred stock ("Series B").

In February 2004, AlgoRx completed a Series C convertible preferred stock financing. AlgoRx issued 109,704,634 shares of Series C preferred stock ("Series C") at a price of \$0.5925 per share for gross consideration of approximately \$65 million. AlgoRx also issued a warrant to purchase 692,658 shares of Series C preferred stock at a purchase price of \$0.5925 per share to the placement agent. AlgoRx valued the warrant at \$285,000 utilizing the Black-Scholes model and reflected the value as an addition and a deduction to Series C convertible preferred stock in the balance sheet. This consideration included cash proceeds of approximately \$55 million which was offset by approximately \$1.4 million of issuance costs and the conversion of \$9.8 million of promissory notes, issued in April 2003, into 16,540,084 shares of Series C preferred stock. In addition, this financing required an adjustment to the conversion prices for the Series A and B convertible preferred stock as a result of antidilution provisions.

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Certain holders of AlgoRx's Series B preferred shares did not participate in the Series C financing. As a result, their holdings, totaling 6,166,154 shares of Series B preferred stock converted to 616,615 shares of AlgoRx common stock.

AlgoRx classified its preferred stock as mezzanine equity because it was redeemable upon the occurrence of an event that is not solely within the control of AlgoRx, including a liquidation, which includes certain mergers and a sale of AlgoRx. Management believes this classification was appropriate since the preferred security holders controlled a majority of votes of AlgoRx's board of directors through direct representation on the board and therefore could authorize a liquidation event.

*Voting*

Series A, B and C stockholders were entitled to the number of votes equal to the number of shares of common stock into which each share of preferred stock is convertible.

*Dividends*

The holders of Series A, B and C were entitled to receive annual dividends at a rate of 8% of the original purchase price in advance of any distributions to common shareholders. Dividends were payable when, and as, declared by the Board of Directors and were noncumulative. No dividends had been declared through December 31, 2005.

*Conversion*

Series A, B and C stockholders were entitled, at any time, to cause their shares to be converted into fully paid and nonassessable shares of common stock. Shares of Series A, B and C were convertible into common stock based on a one-for-ten basis, subject to adjustment for antidilution. The antidilution rights would have gone into effect if stock was sold at a price less than what was paid by the Series A, B or C stockholders. The issuance of the Series C in March 2004 resulted in changes to the conversion ratios of the Series A from 1:0.1 to 1:0.144 and the Series B from 1:0.1 to 1:0.17. Such changes did not result in any additional intrinsic value at the time of adjustment. Additionally, the preferred stock would have converted automatically (i) upon the affirmative election of the holders of at least a majority of the outstanding shares of preferred stock, or (ii) immediately upon the closing of a public offering pursuant to an effective registration statement under the Securities Act of 1933 covering the offer and sale of common stock, which results in aggregate net proceeds to AlgoRx of at least \$30,000,000 and a per share price of at least \$11.80 (appropriately adjusted for any stock dividend, stock split or recapitalization).

*Liquidation*

Before December 15, 2005, the date of the merger between Anesiva and AlgoRx, in the event of any liquidation, dissolution or winding up of AlgoRx, including a change of control, either voluntary or involuntary, the holders of the Series C were entitled to receive, in preference to the Series A and B preferred stock and common stock, an amount equal to one and one-half times the purchase price per share. After payment of the Series C preference amount, the holders of the Series A and Series B were entitled to receive, in preference to the common stock, an amount equal to the purchase price per share, plus all declared but unpaid dividends (appropriately adjusted for any stock dividend, stock split or recapitalization). After payment of these preferential amounts, the remaining assets of AlgoRx were to be distributed among the holders of common and preferred stock (assuming conversion of preferred stock).

In December 2005, pursuant to the merger agreement between Anesiva and AlgoRx, Anesiva issued 13,047,716 shares of Anesiva common stock to AlgoRx preferred stockholders and AlgoRx employees under a

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

retention bonus plan. The Series A, Series B and Series C stockholders and employees received 829,403, 1,378,534, 10,328,369 and 511,410 shares of common stock, respectively and 610,923 shares were held in escrow until June 15, 2006. The Anesiva common stock was value at \$9.44 per share.

*Convertible Notes*

In April 2003, AlgoRx entered into several loan agreements with various financial institutions, whereby the financial institutions agreed to loan AlgoRx an aggregate principal amount of \$9,800,000 that upon closing would be converted into Series C preferred stock at the price at which the Series C preferred stock was sold. The interest on these loans was 1.46% per annum and was payable on December 31, 2004 if the notes were held and not converted on such date. As required by the terms of the loans, they were converted into Series C preferred stock at the Series C preferred stock price of \$0.5925 per share, for a total of 16,540,084 shares of Series C preferred stock in February 2004 and no interest was paid to the financial institutions in accordance with the loan agreements. In accordance with EITF 85-17: *Accrued Interest upon Conversion of Convertible Debt*, AlgoRx recorded interest cost of \$107,310 during 2003 and \$23,847 during 2004 and the corresponding credits were recorded as components of additional paid-in capital.

*Warrant*

In February 2004, in connection with AlgoRx's convertible Series C preferred stock financing transaction, AlgoRx issued a warrant to purchase an aggregate of 692,568 shares of convertible Series C preferred stock at an exercise price of \$0.5925 per share to an investment adviser. In conjunction with the merger between Anesiva and AlgoRx, the warrant was converted into the right to purchase an aggregate of 65,212 shares of Anesiva common stock at an exercise price of \$6.29 per share. The Company valued the warrant at \$354,000 using the Black-Scholes model. The termination date of this warrant is February 19, 2009. The exercise price and the number of shares of common stock issuable upon exercise of the warrant are subject to adjustment upon the occurrence of any stock dividend or stock split.

*Employee Stock Purchase Plan*

The Anesiva Board of Directors adopted the 2003 Employee Stock Purchase Plan (the "Purchase Plan") in December 2003 and Anesiva's stockholders approved it in January 2004 to become effective upon the effective date of the registration statement effecting Anesiva's initial public offering. The Purchase Plan authorizes the issuance of 250,000 post-split shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its affiliates, which amount will be increased on January 1, from 2005 until 2024, by 2% of the number of shares of common stock outstanding on that date or such lesser amount as the Board of Directors may determine. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on that date.

Under the Purchase Plan, employees, subject to certain restrictions, may purchase shares of common stock at 85% of the fair market value at either the date of eligibility for enrollment or the date of purchase, whichever is less. Purchases are limited to 15% of each employee's eligible annual compensation. Under the Purchase Plan, 1,006,049 shares of common stock are available for future issuance at December 31, 2007.

**11. Stock Option Plans**

Pursuant to the merger agreement between Anesiva and AlgoRx, all stock options to purchase shares of common stock of AlgoRx were cancelled. All the information presented in this Note reflects Anesiva's historical equity incentive plans and not those of AlgoRx and have been retroactively adjusted to reflect the one-for-four reverse stock split effected by Anesiva on December 15, 2005.

**Anesiva, Inc.**  
**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The 1999 Equity Incentive Plan was adopted in July 1999 and provides for the issuance of stock options. The Anesiva Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the reservation of an additional 250,000 shares of common stock for issuance under the 1999 Equity Incentive Plan and to rename it the 2003 Equity Incentive Plan (the "2003 Plan"), to become effective upon the effective date of the registration statement. The Board of Directors adopted in October 2005 and the stockholders approved in December 2005 the reservation of an additional 1,800,000 shares of common stock for issuance under the Plan. An aggregate of 3,154,418 shares of common stock was reserved for issuance under the 2003 Plan, which amount will be increased annually for the life of the 2003 Plan on January 1 beginning in 2006, by the lesser of (a) 5% of the number of shares of common stock outstanding on such date and (b) 2,500,000 shares of common stock. However, the board of directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on such date.

Stock options granted under the 2003 Plan may be either incentive stock options, nonstatutory stock options, stock bonuses, or rights to acquire restricted stock. Incentive stock options may be granted to employees with exercise prices of no less than the fair value of the common stock on the grant date and nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 85% of the fair value of the common stock on the grant date, as determined by the board of directors. If, at the time the Company grants an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the board of directors. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated.

The Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the 2003 Nonemployee Directors' Stock Option Plan (the "Directors' Plan"). The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to non-employee directors. The aggregate number of shares of common stock that may be issued pursuant to options granted under the Directors' Plan is 457,500 shares which amount will be increased annually on January 1, from 2006 until 2014, by the number of shares of common stock subject to options granted during the prior calendar year. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased. The Board of Directors adopted in October 2005 and the stockholders approved in December 2005 the reservation of an additional 400,000 shares of common stock for issuance under the Plan.

As of December 31, 2007, the Company had reserved 5,534,941 shares of common stock for issuance under both the Directors' Plan and the 2003 Plan.

Common stock options may include a provision whereby the holder, while an employee, director, or consultant, may elect at any time to exercise the option as to any part or all of the shares subject to the option prior to the full vesting of the option. Any unvested shares so purchased are subject to repurchase by the Company at a price equal to the original purchase price of the stock. This right of repurchase will lapse with respect to the option shares, and each optionee shall vest in his or her option shares, as follows: a minimum of 20% of the option shares upon completion of one year of service measured from the vesting commencement date, and the balance of the option shares in a series of successive equal monthly installments upon the optionee's completion of each of the next 36 months of service thereafter. At December 31, 2007 and 2006, none and 459 shares of common stock acquired through the exercise of options are subject to the Company's right of repurchase, respectively.

**Anesiva, Inc.**  
(a development stage company)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

A summary of activity under the 2003 Plan and Directors' Plan are as follows:

	Shares Available for Grant	Outstanding Options	
		Number of Shares	Weighted-Average Exercise Price Per Share
Balances at January 19, 1999 (Anesiva's Date of Inception)	125,000	—	—
Options granted	(4,373)	4,373	\$ 0.96
Options exercised	—	(937)	\$ 0.96
Balances at December 31, 1999	120,627	3,436	\$ 0.96
Shares reserved	177,456	—	\$ 0.96
Options granted	(106,168)	106,168	\$ 0.96
Options exercised	—	(81,981)	\$ 0.96
Balances at December 31, 2000	191,915	27,623	\$ 0.96
Options granted	(69,213)	69,213	\$ 1.60
Options exercised	—	(63,091)	\$ 1.46
Options canceled	6,094	(6,094)	\$ 0.96
Balances at December 31, 2001	128,796	27,651	\$ 1.42
Additional shares authorized	131,875	—	—
Options granted	(124,844)	124,844	\$ 4.30
Options exercised	—	(30,929)	\$ 1.66
Options canceled	9,093	(9,093)	\$ 3.36
Options shares repurchased	973	—	\$ 1.84
Balances at December 31, 2002	145,893	112,473	\$ 4.39
Additional shares authorized	308,156	—	—
Options granted	(430,390)	430,390	\$ 7.60
Options exercised	—	(122,221)	\$ 5.55
Options canceled	16,136	(16,136)	\$ 4.80
Options shares repurchased	1,942	—	\$ 1.72
Balances at December 31, 2003	41,737	404,506	\$ 7.44
Additional shares authorized	300,000	—	—
Options granted	(276,822)	276,822	\$56.87
Options exercised	—	(16,606)	\$10.96
Options canceled	4,427	(4,427)	\$31.80
Options shares repurchased	2,219	—	\$ 2.36
Restricted shares issued	(38,913)	—	—
Balances at December 31, 2004	32,648	660,295	\$27.91
Additional shares authorized	2,569,431	—	—
Options granted	(1,631,527)	1,631,527	\$13.42
Options exercised	—	(27,214)	\$ 6.93
Options canceled	633,918	(633,918)	\$36.94
Options shares repurchased	8,590	—	\$ 4.53
Restricted shares issued	(19,684)	—	—
Restricted shares canceled	25,497	—	—
Balances at December 31, 2005	1,618,873	1,630,690	\$10.25
Additional shares authorized	1,081,196	—	—
Options granted	(1,776,250)	1,776,250	\$ 7.49
Options exercised	—	(9,347)	\$ 7.84
Options canceled	552,482	(552,482)	\$ 9.18
Options shares repurchased	607	—	\$ 7.07
Restricted shares issued	(24,500)	—	—
Restricted shares canceled	375	—	—
Balances at December 31, 2006	1,452,783	2,845,111	\$ 8.74
Additional shares authorized	1,422,529	—	—
Options granted	(914,552)	914,552	\$ 7.21
Options exercised	—	(32,412)	\$ 7.43
Options canceled	278,046	(278,046)	\$12.18
Restricted shares issued	(166,150)	—	—
Restricted shares canceled	13,080	—	—
Balances at December 31, 2007	2,085,736	3,449,205	\$ 8.07

**Anesiva, Inc.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following table summarizes information about stock options for Anesiva common stock outstanding at December 31, 2007:

Exercise Prices	Options Outstanding			
	Weighted-Avg. Exercise Price	Number Outstanding at Dec. 31, 2007	Weighted-Avg. Remaining Contract Life	Options Vested at Dec. 31, 2007
\$4.80—\$6.73 .....	\$ 5.22	365,713	8.38	120,259
\$6.74—\$8.05 .....	\$ 7.60	2,253,376	7.94	907,869
\$8.06—\$10.20 .....	\$ 9.66	817,616	6.92	555,501
\$10.21—\$64.48 .....	\$64.48	12,500	6.50	10,676
	<u>\$ 8.07</u>	<u>3,449,205</u>	<u>7.74</u>	<u>1,594,305</u>

As of December 31, 2007, there were 10,000 options issued outside of the plans with a weighted-average exercise price of \$4.80 per share. During the year ended December 31, 2007, 20,000 and 10,000 options issued outside of the plan were canceled and exercised, respectively. During the years ended December 31, 2007, the Company granted 17,000 stock options to consultants at a price range of \$6.97 to \$7.20 per share, the fair value of common stock at the date of issuance, none of which were exercised.

In November 2005, Anesiva canceled 353,856 options at a weighted average price of \$38.16 and re-granted 353,856 options at a weighted average price of \$9.80. As a result of this option repricing, Anesiva incurred a non-cash expense of approximately \$47,000 in the year ended December 31, 2005. In conjunction with the merger with AlgorX, Anesiva extended the exercise period for 37,500 options granted to three of its directors and incurred a non-cash expense of approximately \$150,000 in the year ended December 31, 2005. In December 2005, Anesiva accelerated the vesting of 38,655 options of one officer and incurred a non-cash expense of approximately \$63,000.

**12. Employee Benefit Plan**

The Company maintained two defined contribution 401(k) plan available to employees, the Anesiva retirement and Savings Plan and the AlgorX Pharmaceuticals, Inc. 401(k) Plan prior to December 31, 2005. The AlgorX Pharmaceuticals, Inc. 401(k) Plan was terminated in January 2006 as all employees of AlgorX Pharmaceuticals, Inc. became employees of Anesiva, Inc. Employee contributions under both plans are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. Company contributions to the AlgorX Pharmaceuticals, Inc. 401(k) Plan totaled \$64,000 for the years ended December 31, 2005. For the year ended December 31, 2007 and 2006, the Company contributions to the Anesiva retirement and Savings Plan were \$273,000 and \$171,000, respectively. Company contributions under both plans as reported in cumulative losses in the development stage were \$624,000 for the period from March 6, 2001 (inception) to December 31, 2007. For the year ended December 31, 2007 and 2006, the Company matched \$0.50 on each dollar of employee contribution to a maximum of \$3,500 capped at 17% and 6% of an employee annual compensation, respectively.

**13. Income Taxes**

As of December 31, 2007 and 2006, the Company had deferred tax assets of approximately \$46.9 million and \$128.1 million, respectively. Realization of the deferred tax assets is dependent upon the Company generating future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the

**Anesiva, Inc.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

deferred tax assets have been fully offset by a valuation allowance at December 31, 2007 and 2006. The net valuation allowance decreased by approximately, \$81.2 million, increased by \$18.6 million and \$86.1 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to net operating loss carryforwards. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 32,837	\$ 100,963
Research credits .....	1,311	16,747
Deferred stock compensation .....	11,692	8,574
Other temporary differences .....	1,070	1,844
Total gross deferred tax assets .....	46,910	128,128
Valuation allowance .....	(46,910)	(128,128)
Net deferred tax assets .....	\$ —	\$ —

As of December 31, 2007, the Company had federal net operating loss carryforwards and research carryforwards for federal income tax purposes of approximately \$84.9 million and approximately \$46,500 which expire beginning in the year 2018. As of December 31, 2007, the Company had state net operating loss carryforwards and research carryforwards of approximately \$54.2 million and \$3.9 million. The state net operating losses start to expire in 2008 and the research carryforwards have no expiration date.

Utilization of the net operating loss carryforwards and credit carryforwards may be subject to a substantial annual limitation due to the limitations set forth in Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company concluded a detailed analysis to determine whether ownership changes under Section 382 of the Internal Revenue Code have occurred in the Company and its predecessor entities, AlgoRx Pharmaceutical, Inc. and Corgentech Inc. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards and credit carryforwards attributable to periods before the change. The Company concluded that approximately \$230.6 million and \$10.3 million in federal net operating loss carryforwards and credit carryforwards and approximately \$216.0 million and \$7.7 million in state net operating loss carryforwards and credit carryforwards are significantly limited to offset future taxable income, if any.

The Company had unrecognized tax benefit of approximately \$1.3 million and \$2.0 million as of January 1, 2007 and December 31, 2007, respectively, all of which is offset by a full valuation allowance. These unrecognized tax benefits, if recognized, would affect the effective tax rate. There was no interest or penalties accrued at the adoption date and at December 31, 2007.

The Company files income tax returns in the US federal jurisdiction and California tax jurisdictions. The tax years 1997 to 2007 remain open to examination by the US and state tax authorities.

**Anesiva, Inc.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

A reconciliation of the change in the unrecognized tax benefit balance from January 1, 2007 to December 31, 2007 is as follows (in thousands):

	<b>Federal and State Tax</b>
Balance as of January 1, 2007 .....	\$1,275
Additions for tax positions related to current year .....	699
Additions for tax positions related to prior years .....	—
Balance at December 31, 2007 .....	1,974
Less: unrecognized tax benefits attributable to temporary items included above .....	—
Total unrecognized tax benefits as of December 31, 2007, if recognized, would impact the effective tax rate .....	\$1,974

**14. Loss Per Share**

The following table sets forth the computation of basic and diluted net loss attributable to common stockholders per share:

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except share and per share amounts)		
Numerator for basic and diluted net loss per share—net loss .....	\$ (59,282)	\$ (55,567)	\$ (33,518)
Denominator:			
Weighted-average common shares outstanding .....	28,024,289	20,648,878	1,985,750
Less: Weighted-average unvested common shares subject to repurchase .....	(211)	(5,560)	(799)
Denominator for basic and dilutive net loss per share—weighted average shares .....	28,024,078	20,643,318	1,984,951
Basic and diluted net loss per share .....	\$ (2.12)	\$ (2.69)	\$ (16.89)

The following table shows dilutive common share equivalents outstanding, which are not included in the above historical calculations, as the effect of their inclusion is anti-dilutive during each period. Restricted stock that is not yet vested is included as dilutive common share equivalents because the Company considers such securities as the equivalent of stock options.

	Year Ended December 31,		
	2007	2006	2005
Restricted stock .....	152,320	26,061	11,311
Escrow stock .....	—	—	610,923
Warrants .....	65,212	65,212	65,212
Plan Options .....	3,449,205	2,845,111	1,370,690
Out of Plan Options .....	10,000	40,000	40,000
	3,676,737	2,976,384	2,098,136

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**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The pro forma basic and diluted net loss per share shows the basic and diluted net loss per share had the AlgoRx convertible preferred stock been converted into Anesiva common stock. The following table sets forth the computation of pro forma basic and diluted net loss attributable to common stockholders per share for the year ended December 31, 2005 (in thousands, except share and per share amounts):

Numerator for pro forma basic and diluted net loss per share—net loss .....	\$ (33,518)
Denominator:	
Weighted-average pro forma common shares outstanding .....	12,763,928
Less: Weighted-average pro forma unvested common shares subject to repurchase .....	<u>(799)</u>
Denominator for pro forma basic and dilutive net loss per share—weighted average shares .....	<u>12,763,129</u>
Pro forma basic and diluted net loss per share .....	<u>\$ (2.63)</u>

**Shares Reserved for Issuance**

The Company has reserved shares of common stock for future issuance at December 31, 2007 as follows:

Options outside plans .....	10,000
2003 Plan and Director's Plan .....	5,534,941
Warrant .....	65,212
Purchase Plan .....	<u>1,006,049</u>
	<u>6,616,202</u>

**15. Selected Quarterly Financial Data (Unaudited)**

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands)			
<b>2007</b>				
Contract revenues .....	\$ —	\$ —	\$ 50	\$ 1
Net loss .....	(11,678)	(13,838)	(16,057)	(17,709)
Basic and diluted net loss per common share .....	(0.43)	(0.51)	(0.58)	(0.60)
<b>2006</b>				
Contract revenues .....	\$ —	\$ —	\$ —	\$ 89
Net loss .....	(14,562)	(13,803)	(11,887)	(15,315)
Basic and diluted net loss per common share .....	(0.75)	(0.70)	(0.59)	(0.65)

**Anesiva, Inc.**  
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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**16. Subsequent Events**

In February 2008, the Company entered into an agreement granting an exclusive license to Sigma-Tau for the marketing and distribution of Zingo in Belgium, France, Germany, Italy, Luxembourg and the Netherlands. Under the terms of the agreement, Sigma-tau will oversee all necessary regulatory filings and will be responsible for all marketing and sales of Zingo in their territory. The Company received a refundable upfront payment and will sell Zingo to Sigma-Tau for a transfer price and may earn sales milestone payments.

In February 2008, the Company contributed approximately \$515,000 to its Joint Venture with Wanbang Pharma, Wanbang Anesiva (Jiangsu) Pharmaceutical Co., Ltd. in accordance with the Cooperative Joint Venture Contract as the agreement became effective upon approval by the Chinese commerce government authorities in January 2008. The Company is committed to invest up to approximately \$1.0 million in the Joint Venture.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 14, 2008.

ANESIVA, INC.

By:           /s/ JOHN P. MCLAUGHLIN            
John P. McLaughlin  
Chief Executive Officer

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ JOHN P. MCLAUGHLIN John P. McLaughlin	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 14, 2008
/s/ JEAN-FRÉDÉRIC VIRET Jean-Frédéric Viret, Ph.D.	Vice President and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 14, 2008
/s/ RODNEY A. FERGUSON Rodney A. Ferguson, Ph.D.	Chairman of the Board	March 14, 2008
/s/ JAMES N. CAMPBELL James N. Campbell, M.D.	Director	March 14, 2008
/s/ THOMAS J. COLLIGAN Thomas J. Colligan	Director	March 14, 2008
/s/ CARTER H. ECKERT Carter H. Eckert	Director	March 14, 2008
/s/ JAMES A. HARPER James A. Harper	Director	March 14, 2008
/s/ DANIEL S. JANNEY Daniel S. Janney	Director	March 14, 2008
/s/ ARNOLD L. ORONSKY Arnold L. Oronsky, Ph.D.	Director	March 14, 2008
/s/ MICHAEL F. POWELL Michael F. Powell, Ph.D.	Director	March 14, 2008
/s/ ROBERT L. ZERBE Robert L. Zerbe, M.D.	Director	March 14, 2008

## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1(1)	Agreement and Plan of Merger among Corgentech Inc., Element Acquisition Corp. and AlgoRx Pharmaceuticals, Inc. dated September 23, 2005.
3.1(2)	Restated Certificate of Incorporation.
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation
3.3(3)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(4)	Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2(5)	Specimen stock certificate.
10.1(6)*	2003 Equity Incentive Plan.
10.2(7)*	2003 Non-Employee Directors' Stock Option Plan.
10.3(5)*	2003 Employee Stock Purchase Plan.
10.4(5)	Lease Agreement, dated March 16, 2000, between Gateway Center, LLC and Corgentech Inc.
10.5(5)	Sublease, dated March 11, 2002, between Michael Gurfinkel and Corgentech Inc.
10.6(5)	Sublease, dated May 15, 2003, between Coulter Pharmaceuticals, Inc. and Corgentech Inc.
10.7(5)	Lease, dated November 7, 1997, between Coulter Pharmaceuticals, Inc. and HMS Gateway Office L.P., as amended by the First Amendment to Lease Agreement, dated November 10, 1998, and Second Amendment to Lease Agreement, dated May 19, 2000.
10.8	Reserved.
10.9	Reserved.
10.10	Reserved.
10.11(5)	Master Security Agreement, dated February 3, 2003, between GE Capital Corporation and Corgentech Inc., as amended.
10.12(6)	Amended and Restated Investor Rights Agreement, dated October 10, 2003.
10.13(5)	Form of Indemnity Agreement.
10.14(5)*	Employment Letter, dated November 29, 1999, with John P. McLaughlin.
10.15	Reserved.
10.16	Reserved.
10.17(5)*	Termination of Preemptive Rights and Registration Rights Agreement, dated May 17, 2002, between John P. McLaughlin and Corgentech Inc.
10.18(5)*	Employment Letter, dated August 18, 2000, with Leslie M. McEvoy.
10.19(5)*	Promissory Note, dated June 28, 2001, issued by Leslie M. McEvoy to Corgentech Inc.
10.20	Reserved.
10.21(5)*	Letter Agreement, dated June 30, 2001, with Leslie M. McEvoy.
10.22	Reserved.

<u>Exhibit Number</u>	<u>Description of Document</u>
10.23(5)*	Stock Pledge Agreement, dated August 28, 2001, with Leslie M. McEvoy.
10.24(5)*	Employment Letter, dated October 18, 2001, with Richard P. Powers.
10.25(5)*	Promissory Note, dated December 20, 2001, issued by Richard P. Powers to Corgentech Inc.
10.26(5)*	Stock Pledge Agreement, dated December 20, 2001, with Richard P. Powers.
10.27(8)*	Employment Agreement with Ronald M. Burch, dated December 6, 2005 and effective December 15, 2005.
10.28(5)*	Employment Letter, dated July 2, 2002, with James Z. Huang.
10.29(5)*	Letter Agreement, dated October 11, 2002, with James Z. Huang.
10.30(5)*	Promissory Note, dated October 11, 2002, issued by James Z. Huang to Corgentech Inc.
10.31(5)*	Stock Pledge Agreement, dated October 11, 2002, with James Z. Huang.
10.32(9)*	Employment Letter, dated April 30, 2004, with Patrick Broderick.
10.33(10)*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2003 Equity Incentive Plan.
10.34(11)*	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2003 Equity Incentive Plan.
10.35(12)*	Form of Grant Notice and Stock Option Agreement for the 2003 Non-Employee Directors' Stock Option Plan.
10.36(13)	Non-employee director cash compensation arrangement.
10.37(14)	Escrow Agreement, dated December 15, 2005 between Corgentech Inc. and Mellon Investor Services.
10.38(15)	Lease Agreement dated August 27, 1997, by and between AlgoRx Technologies, Inc. (formerly PowderJect Technologies, Inc.) and John Arrillaga, or his Successor Trustee, UTA dated 07/20/77 (the John Arrillaga Survivor's Trust) as amended and Richard T. Peery, Trustee, or his Successor Trustee, UTA 7/20/77 (Richard T. Peery Separate Property Trust) as amended (Exhibit 10.8 to File No. 333-120757).
10.39(15)	Lease dated May 10, 2004, between AlgoRx Pharmaceuticals, Inc. and 500 Plaza Drive Corp. (exhibit 10.9 to File No. 333-120757).
10.41(15)	License Agreement entered into as of August 28, 2001, among AlgoRx Pharmaceuticals, Inc. and James N. Campbell, M.D., Richard Meyer, M.S. and Marco Pappagallo, M.D. (exhibit 10.10 to File No. 333-120757).
10.42(15)	License Agreement entered into as of August 28, 2001, between AlgoRx Pharmaceuticals, Inc. and Marco Pappagallo, M.D. (Exhibit 10.11 to File No. 333-120757).
10.43(15)††	License Agreement entered into as of March 22, 2002, by and between AlgoRx Pharmaceuticals, Inc. and PowderJect Research Limited (Exhibit 10.12 to File Number 333-120757).
10.44(15)††	First Amendment to License Agreement entered into as of July 7, 2003, between AlgoRx Pharmaceuticals, Inc. and PowderJect Research Limited (Exhibit 10.13 to File No. 333-120757).
10.45(15)	Assignment, Assumption and Consent Agreement made as of May 14, 2004, by and among PowderMed Limited, PowderJect Research Limited, PowderJect Technologies Limited, AlgoRx Pharmaceuticals, Inc. and AlgoRx Technologies, Inc. (Exhibit 10.14 to File No. 333-120757).

<u>Exhibit Number</u>	<u>Description of Document</u>
10.46(15)	Letter Agreement entered into as of September 30, 2004, between AlgoRx Pharmaceuticals, Inc. and PowderJect Research Limited (Exhibit 10.15 to File No. 333-120757).
10.47(15)††	Supply Agreement entered into as of March 22, 2002, between AlgoRx Pharmaceuticals, Inc. and PowderJect Research Ltd. (Exhibit 10.16 to File No. 333-120757).
10.48(15)††	First Amendment to Supply Agreement entered into as of July 7, 2003, between AlgoRx Pharmaceuticals, Inc. and PowderJect Technologies Limited (Exhibit 10.17 to File No. 333-120757).
10.49(15)††	Collaboration, Development and License Agreement made as of October 28, 2004, between AlgoRx Pharmaceuticals, Inc. and Bridge Pharma, Inc. (Exhibit 10.18 to File No. 333-120757).
10.50(15)	Lease Modification Agreement dated January 17, 2005 between AlgoRx Pharmaceuticals, Inc. and 500 Plaza Drive Corp. (Exhibit 10.20 to File No. 333-120757).
10.51(15)	Lease dated January 12, 2005 between AlgoRx Pharmaceuticals, Inc. and Sunnyvale Village Associates (Exhibit 10.21 to File No. 333-120757).
10.52(3)††	Letter Agreement, dated May 20, 2006, between Mikron Corporation and Anesiva, Inc.
10.53(16)	Sublease Extension, dated August 17, 2006, by and among the Registrant and GlaxoSmithKline plc, as Successor in Interest to Coulter Pharmaceuticals.
10.54(17)†	Loan and Security Agreement, dated August 30, 2007, by and among the Registrant and General Electric Capital Corporation.
10.55(17)†	Promissory Note, dated August 30, 2007, issued to General Electric Capital Corporation.
10.56††	Promotional Agreement, dated October 9, 2007, by Anesiva, Inc. and Sagent Pharmaceuticals, Inc.
10.57††	Cooperative Joint Venture Contract, dated October 11, 2007, by Anesiva, Inc. and Lau, Yat Ming and Wanbang Biopharmaceutical Co. Ltd.
10.58(18)*	Executive Change in Control and Severance Benefit Plan.
10.59(19)	Common Stock Purchase Agreement, dated June 19, 2006, between Corgentech Inc. and Azimuth Opportunity Ltd.
21.1	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (contained on signature page).
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.
31.2	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(a) of the Securities and Exchange Act of 1934, as amended.
32.1**	Certification of Chief Executive Officer, as required by Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2**	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

- (1) Filed as Exhibit 1.1 to our Current Report on Form 8-K, (File No. 000-50573), dated September 26, 2005, filed on September 26, 2005 and incorporated by reference herein.
  - (2) Filed as Exhibit 3.2 to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed on December 4, 2003, and incorporated by reference herein.
  - (3) Filed as Exhibit 3.2 to our Quarterly Report on Form 10-Q (File No. 000-50573), for the quarter ended June 30, 2006, filed on August 10, 2006, and incorporated by reference herein.
  - (4) Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 000-50573), filed on February 11, 2008, and incorporated by reference herein.
  - (5) Filed as the like numbered exhibit to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed on December 4, 2003, and incorporated by reference herein.
  - (6) Filed as Exhibit 10.48 to our Current Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on December 16, 2005, and incorporated by reference herein.
  - (7) Filed as Exhibit 10.49 to our Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on December 16, 2005, and incorporated by reference herein.
  - (8) Filed as Exhibit 10.50 to our Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on December 16, 2005, and incorporated by reference herein.
  - (9) Filed as Exhibit 10.32 to our Quarterly Report on Form 10-Q (File No. 000-50573), for the quarter ended June 30, 2004, filed on August 12, 2004, and incorporated by reference herein.
  - (10) Filed as Exhibit 10.35 to our Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on December 16, 2005, and incorporated by reference herein.
  - (11) Filed as Exhibit 10.36 to our Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on February 24, 2005, and as amended as filed as Exhibit 99.1 to our Report on Form 8-K, filed on February 9, 2007, and incorporated by reference herein.
  - (12) Filed as Exhibit 10.37 to our Report on Form 8-K (File No. 000-50573), dated December 15, 2005, filed on December 16, 2005, and incorporated by reference herein.
  - (13) Filed as Exhibit 10.38 to our Annual Report on Form 10-K, as amended (File No. 000-50573), for the year ended December 31, 2004, filed on March 22, 2005, and incorporated by reference herein.
  - (14) Filed as Exhibit 2.4 to InterWest Partners VIII, LP's Schedule 13D (File No. 005-79795), filed on December 27, 2005, and incorporated by reference herein.
  - (15) Filed as an exhibit under the number indicated to AlgoRx Pharmaceuticals, Inc.'s Registration Statement on Form S-1, as amended (File No. 333-120757), filed on November 24, 2004, and incorporated by reference herein.
  - (16) Filed as the like numbered exhibit to our Report on Form 8-K (File No. 000-50573), dated August 17, 2006, filed on August 23, 2006, and incorporated by reference herein.
  - (17) Filed as the liked-numbered exhibit to our Current Report of Form 8-K, filed with the SEC on September 6, 2007, and incorporated herein by reference.
  - (18) Filed as Exhibit 10.44 to our Quarterly Report on Form 10-Q (File No. 000-50573), for the quarter ended June 30, 2005, filed on August 4, 2005, and incorporated by reference herein.
  - (19) Filed as Exhibit 99.2 to our Report on Form 8-K (File No. 000-50573), dated June 19, 2006, filed on June 20, 2006, and incorporated by reference herein.
- † Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from this filing and have been filed separately with the Securities and Exchange Commission.
- †† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this filing and have been filed separately with the Securities and Exchange Commission.
- \* Management contract, compensatory plan or arrangement.
- \*\* The certifications attached as Exhibit 32.1 and Exhibit 32.2 accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Corgentech Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

**ANESIVA, INC.**  
**LIST OF SUBSIDIARIES**

AlgoRx Pharmaceuticals, Inc.

Anesiva Hong Kong Limited

**CONSENT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-112735, 333-122016, 333-130402, 333-131060 and 333-141226) pertaining to the Anesiva, Inc. 2003 Equity Incentive Plan, the 2003 Non-Employee Directors' Stock Option Plan, the 2003 Employee Stock Purchase Plan, and the Non-Plan Option Grants of our reports dated March 14, 2008 with respect to the consolidated financial statements of Anesiva, Inc., and the effectiveness of internal control over financial reporting of Anesiva, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2007.

*/s/* ERNST & YOUNG LLP

Palo Alto, California  
March 14, 2008

**CERTIFICATION**

I, John P. McLaughlin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Anesiva, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008

/s/ JOHN P. MCLAUGHLIN

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**John P. McLaughlin**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

**CERTIFICATION**

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Annual Report on Form 10-K of Anesiva, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2008

/s/ JEAN-FRÉDÉRIC VIRET

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Jean-Frédéric Viret, Ph.D.  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John P. McLaughlin, Chief Executive Officer of Anesiva, Inc., a Delaware corporation (the "Company") hereby certifies that, to the best of his knowledge, as follows:

The Company's Annual Report on Form 10-K for the period ended December 31, 2007, to which this Certification is attached as Exhibit 32.1 (the "*Annual Report*") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of this 14<sup>th</sup> day of March 2008.

By: \_\_\_\_\_ /s/ JOHN P. McLAUGHLIN

John P. McLaughlin  
Chief Executive Officer  
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), has been provided to Anesiva, Inc. and will be retained by Anesiva, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jean-Frédéric Viret, Vice President and Chief Financial Officer of Anesiva, Inc., a Delaware corporation (the "Company") hereby certifies that, to the best of his knowledge, as follows:

The Company's Annual Report on Form 10-K for the period ended December 31, 2007, to which this Certification is attached as Exhibit 32.2 (the "*Annual Report*") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of this 14<sup>th</sup> day of March 2008.

By:           /s/ JEAN-FRÉDÉRIC VIRET            
Jean-Frédéric Viret, Ph.D.  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), has been provided to Anesiva, Inc. and will be retained by Anesiva, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

## Corporate Directory

### Management

**John P. McLaughlin**  
Chief Executive Officer  
and Director

**Patrick A. Broderick**  
Vice President, General Counsel  
and Corporate Secretary

**James R. Carr, Pharm.D.**  
Vice President, Marketing

**Nancy E. Donahue**  
Senior Vice President,  
Marketing

**Susan M. Kramer, Dr.P.H.**  
Vice President, Preclinical  
Development

**Samantha R. Miller**  
Vice President,  
Business Development

**Melissa Morandi**  
Vice President,  
Quality Assurance

**John X. Regan**  
Senior Vice President,  
Operations

**Yvonne Richardson**  
Vice President,  
Manufacturing

**Jean-Frédéric Viret, Ph.D.**  
Vice President and  
Chief Financial Officer

### Board of Directors

**Rodney A. Ferguson, J.D., Ph.D.**  
Chairman of the Board  
Managing Director,  
Panorama Capital

**James N. Campbell, M.D.**  
Director of the Blaustein Pain  
Treatment Center at Johns Hopkins  
University School of Medicine

**Thomas J. Colligan**  
Retired Vice Chairman,  
PricewaterhouseCoopers LLP

**Carter H. Eckert**  
Former Chairman and  
Chief Executive Officer,  
IMPATh Inc.

**James A. Harper**  
Retired Group Vice President,  
Global Marketing and Sales,  
Eli Lilly and Company

**Daniel S. Janney**  
Managing Director,  
Alta Partners

**John P. McLaughlin**  
Chief Executive Officer and  
Director, Anesiva

**Arnold L. Oronsky, Ph.D.**  
General Partner,  
InterWest Partners

**Michael F. Powell, Ph.D.**  
Managing Director,  
Sofinnova Ventures

**Robert L. Zerbe, M.D.**  
Chief Executive Officer,  
QuatRx Pharmaceuticals

### Corporate Counsel

**Cooley Godward Kronish LLP**  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306

### Independent Accountants

**Ernst & Young LLP**  
1001 Page Mill Road  
Building 1, Suite 200  
Palo Alto, CA 94304

### Annual Stockholders Meeting

Anesiva's annual meeting of  
stockholders will be held at  
9:00 a.m. on **May 8, 2008** at:  
**Marriott San Francisco Airport**  
1800 Old Bayshore Highway  
Burlingame, CA

### Company Contact

Anesiva Inc.  
650 Gateway Boulevard  
South San Francisco, CA 94080  
Phone: 650.624.9600  
Fax: 650.624.7540  
investors@anesiva.com

### Registrar & Transfer Agent

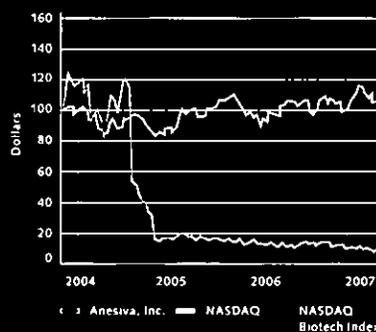
**BNY Mellon Shareowner Services**  
P.O. Box 359015  
Pittsburgh, PA 15252  
Toll-free: 800.240.0593  
From outside U.S.: 201.680.6578  
TDD toll-free: 800.231.5469  
TDD from outside U.S.: 201.680.66

### Quarterly Reporting &

#### Other Information

Anesiva's Form 10-K and other SEC  
filings, news releases and other  
information regarding the company  
and its technology are available on  
the Internet: [www.anesiva.com](http://www.anesiva.com)

### Stock Comparison Chart



This annual report includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions are intended to identify such forward-looking statements. Forward-looking statements in this annual report include matters that involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to differ materially from results expressed or implied by this press release. Such risk factors include, among others: the timing and results of our clinical trials, whether Anesiva is able to manufacture its products on commercially reasonable terms, whether Anesiva can secure FDA approval for the use of Zingo in adults, the degree to which Zingo gains market acceptance, and our regulatory approval strategy for Adlea. Actual results may differ materially from those contained in the forward-looking statements in this annual report.

Anesiva undertakes no obligation and does not intend to update these forward-looking statements to reflect events or circumstances occurring after this annual report. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. All forward-looking statements are qualified in their entirety by this cautionary statement. The Anesiva logo, Zingo and Adlea are trademarks of Anesiva, Inc.



Anesiva, Inc.  
650 Gateway Boulevard  
South San Francisco, CA 94080

W W W . A N E S I V A . C O M

**END**