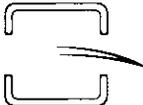




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 JAVELIN



*Enriching Quality of Life Through Enhanced Pain Relief*

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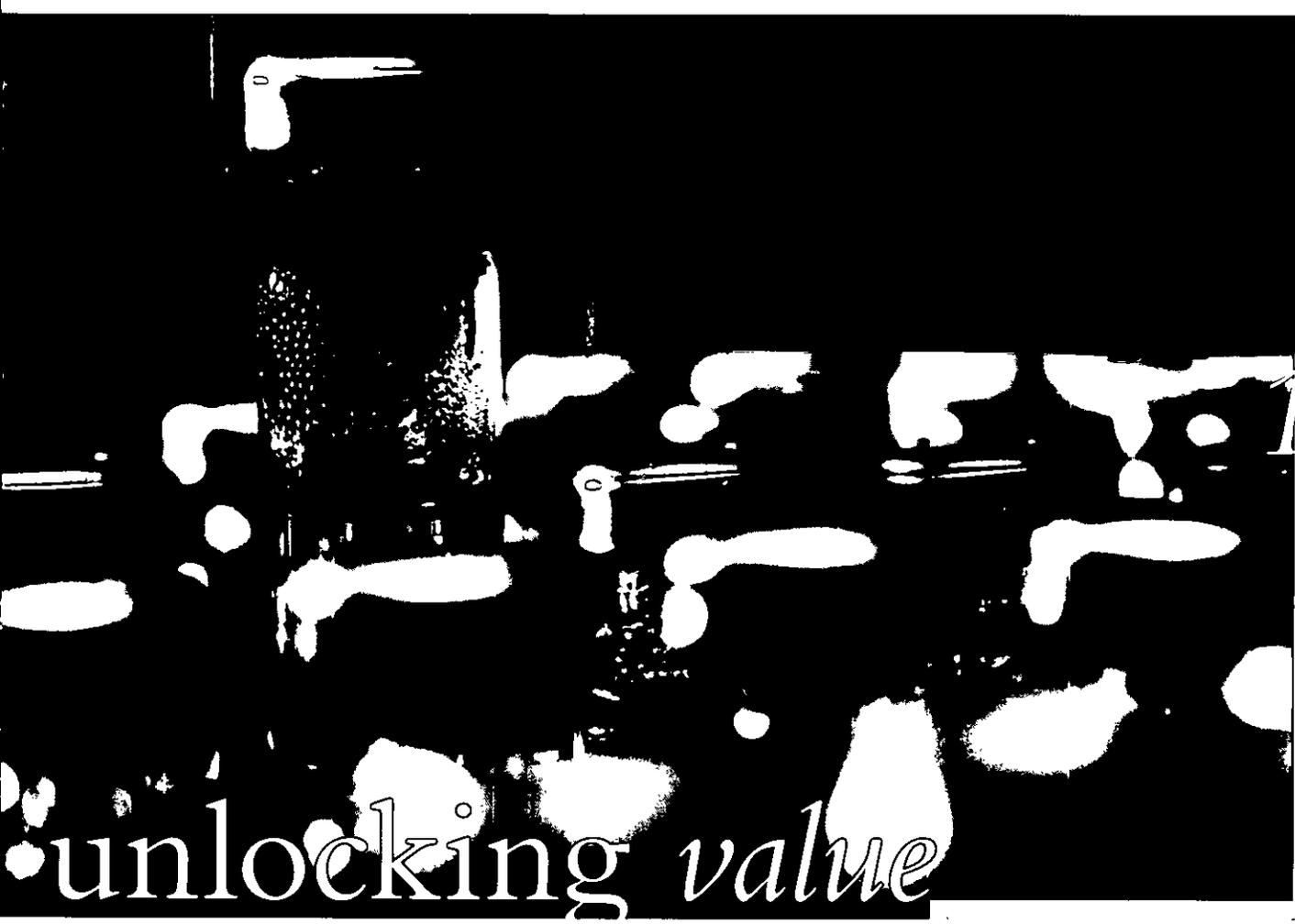
# Welcome to Javelin.

Javelin is a specialty pharmaceutical company that applies innovative proprietary technologies to develop new drugs and improved formulations of existing drugs that target current unmet and underserved medical need in the pain management market.

Javelin's product candidates address the acute moderate-to-severe pain medication market segment. We are developing differentiated pain control products that provide the flexibility and versatility required to address the limitations of existing prescription pain medications in supervised health care settings.

Indications under development include post-operative pain, orthopedic injury pain, procedural pain, burn pain and trauma. Our product candidates offer enhanced pain relief, fewer adverse side effects and faster relief of pain compared to other currently available treatments.

Javelin has three late stage product candidates in development: Dylject™ (diclofenac sodium, injectable), Rylomine™ (intranasal morphine) and PM-150 (intranasal ketamine).



Javelin's development program is designed to support global registration, with special emphasis placed upon U.S. and European filings for drug approval and product registration. Our product candidates address the acute moderate-to-severe pain medication market segment.

Utilizing proprietary technologies, Javelin minimizes development risk and maximizes commercial opportunity through novel administration routes, novel formulations and new labeling for existing FDA-approved drugs.

Our three product candidates, their indications as well as their stages of clinical development are:

Product Candidate	Territory	Indication	Development Stage
Dyloject™ <i>(injectable diclofenac)</i>	U.S.	Postoperative pain	Phase III
	Europe	Postoperative pain, Anti-inflammatory	MAA Review
PMI-150 <i>(intranasal ketamine)</i>	U.S.	Acute moderate-to-severe pain	Completing registration studies
Rylomine™ <i>(intranasal morphine)</i>	U.S.	Acute moderate-to-severe pain	Phase III

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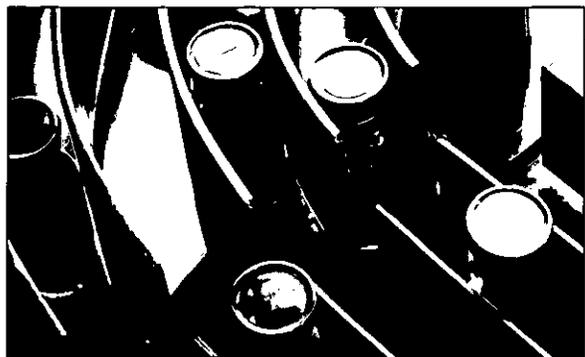
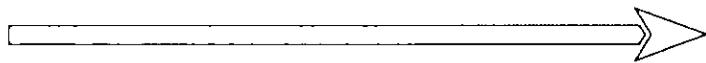
## Dear Shareholders:

I am pleased to report that during 2006 the value of our Company increased substantially, reflecting our significant progress towards becoming a commercial enterprise. All three of our late stage product candidates advanced steadily in clinical and regulatory development. Meetings with the FDA during 2006 provided us with a clear pathway to regulatory approval for Dyloject™ (diclofenac for injection) and Rylomine™ (intranasal morphine). Ongoing communication with European authorities likewise kept us on track for approval and commercial launch of Dyloject in 2007. Continuing dialog with the US Department of Defense allowed us to collaborate towards a clinical and regulatory strategy aimed at approval of PMI-150 (intranasal ketamine) for civilian emergency and military use, with subsequent applications as an adjunct to opioids, and for breakthrough pain in cancer.

To support this exciting progress on multiple fronts, during the past year we expanded our commercial, manufacturing, and financial infrastructures in anticipation of our transition from a drug development company to a commercial one with offices in both Cambridge, Massachusetts and Cambridge, UK. To handle the Company's increasing work load and expanded scope of activities, including the anticipated Dyloject product launch, we are in the process of growing our infrastructure. We have taken the initial steps to build a sales force beginning in the UK.

Javelin employees share the enthusiasm and dedication for Javelin that inspired many of you to become shareholders. We welcomed outstanding new Directors, filling out a Board that brings unparalleled depth of experience and success in development and commercialization of pharmaceutical products. In 2006 we were fortunate to present results of our key clinical trials at prestigious scientific and industry conferences. Several of our clinical trial results were submitted for publication and are now in press in peer-reviewed professional journals of international impact. Further, our coverage by Wall Street research analysts is expanding. At present, we are looking forward to releasing top line results from two pivotal Phase 3 trials in our Dyloject and Rylomine programs, and have initiated the first of our final pharmacokinetic studies necessary to submit the NDA for PMI-150.

target current unmet and underserved medical need in the pain management market



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We remain deeply grateful to our early investors for their vision and continued loyal backing. Personally, I feel exhilarated and privileged to work with the many talented people within Javelin including its founders, senior management and employees at every level, Directors, and our outside colleagues and consultants who provide special legal, financial, scientific and regulatory expertise. All of us at Javelin share with them, and with you our shareholders, our commitment to grow our Company's value as we grow nearer to marketing, distribution and sales of innovative products to meet the still-underserved needs of patients and their families in pain.

*Daniel B. Carr*

Daniel B. Carr, MD  
*Chief Executive Officer & Chief Medical Officer*

Javelin Pharmaceuticals, Inc.  
May 2007

# Leadership—it all starts here

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## **Daniel B. Carr, MD** *Chief Executive Officer & Chief Medical Officer*

Dr. Carr became CEO in September 2005; he joined the Company as Chief Medical Officer a year earlier. Dr. Carr is a founding director of the MS Program in Pain Research, Education & Policy of Tufts University School of Medicine. A principal investigator on numerous clinical studies of pain and analgesia, Dr. Carr is also the recipient of many awards and honors from leading professional organizations and healthcare institutions worldwide. He is a sought-after advisor and speaker at Pain Industry events. Dr. Carr has authored or contributed to over 300 articles, book chapters and books on therapies for pain. He joined Javelin from the position of Saltonstall Professor of Pain Research in the Department of Anesthesia at Tufts-New England Medical Center. Dr. Carr holds an MD with honors (Alpha Omega Alpha) from Columbia University and a MS and BS (Honors) in Physics, also from that institution.

## **Fred H. Mermelstein, PhD** *President*

Dr. Mermelstein is a co-founder of Javelin and has served on the Board of Directors and as President from its inception. Formerly, Dr. Mermelstein served as Director of Venture Capital for Paramount Capital Investments, LLC. Dr. Mermelstein is a member of Orion Biomedical GP, LLC. He also serves as a director of Cardiome Pharma, Inc.; Adherex Technologies, Inc.; and previously the Jordan Heart Foundation. From February 1997 until January 2000, Dr. Mermelstein served as a director and Chief Science Officer of PolaRx BioPharmaceuticals, an oncology-based biopharmaceutical company. Dr. Mermelstein holds a dual PhD in Pharmacology and Toxicology from Rutgers University and University of Medicine and Dentistry of New Jersey (UMDNJ) Robert Wood Johnson Medical School. He completed his post-doctoral training supported by two grant awards: a National Institutes of Health fellowship and a Howard Hughes Medical Institute fellowship in the Department of Biochemistry at UMDNJ Robert Wood Johnson Medical School.

## **Stephen J. Tulipano, CPA, MBA** *Chief Financial Officer*

Stephen J. Tulipano joined Javelin in May 2006 as its Chief Financial Officer. In this capacity, he oversees all of the Company's finance functions, including treasury, tax, accounting, financial planning, reporting, controls and Sarbanes-Oxley compliance. Previously, he was Director of Corporate Accounting at Biogen Idec. During his tenure at Biogen Idec, which spanned over seven years, he was responsible for accounting, external reporting, establishment of new accounting and internal control initiatives worldwide and developing innovative business approaches to partnered programs and business development opportunities. Prior to joining Biogen, he served as External Reporting Manager for Digital Equipment Corporation. Mr. Tulipano is a Certified Public Accountant, a member of the American Institute of Certified Public Accountants (AICPA) and the Massachusetts Society of Certified Public Accountants and holds a MBA from Suffolk University. He is also a veteran of the United States Navy and the United States Army National Guard.

## **David B. Bernstein, Esq.** *General Counsel & Chief Intellectual Property Counsel*

Mr. Bernstein joined Javelin in April 2006 and serves as the company's General Counsel and Chief Intellectual Property Counsel. Prior to joining the company, Mr. Bernstein held the same position at U.S. Genomics. Formerly, Mr. Bernstein co-founded the Intellectual Property section at the law firm Mintz Levin Cohn Ferris Glovsky & Popeo, and served as section chairperson. Mr. Bernstein has also held the position of Intellectual Property Counsel for 3M Company, and was a partner at Wolf, Greenfield & Sacks, a law firm specializing in intellectual property. He has extensive experience in the biopharmaceutical sector, including work in biotechnology, biomaterials, and medical devices. Furthermore, his experience includes semiconductor and microfabrication technologies. He has a background in obtaining and enforcing patents, trademarks and copyrights and intellectual property licensing. Mr. Bernstein holds a BS in engineering from Yale University and a JD from Franklin Pierce Law Center.

## **Curtis Wright IV, MD, MPH** *Executive Vice President, Risk Management & Regulatory Affairs*

Dr. Wright joined Javelin in 2005. Dr. Wright previously served as Vice President of Clinical and Regulatory Affairs for Adolor Corporation and Executive Director of Risk Assessment for Purdue Pharma. Dr. Wright is a former FDA division director who served at the FDA from 1989 to 1997 in a variety of capacities within its Center for Drug Evaluation and Research. A well-known national expert in the regulation and safety of drugs with abuse potential, he is the author of a number of peer-reviewed publications on drug development as well as substance abuse. He is the recipient of many awards and honors including election to Alpha Omega Alpha, the medical honor society; Delta Omega Alpha, the public health honors society; the FDA Center Director's Award for Exemplary Contribution; the HHS Secretary's Award for Distinguished Service; and selection as Outstanding Clinical Pharmacology Professor at the Uniformed Services University of the Health Sciences.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
**FORM 10-K**

(As amended through Amendment No.1)

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

For the fiscal year ended December 31, 2006

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

COMMISSION FILE NUMBER 0-31114

**JAVELIN PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

88-0471759

(State or other jurisdiction of incorporation or organization)

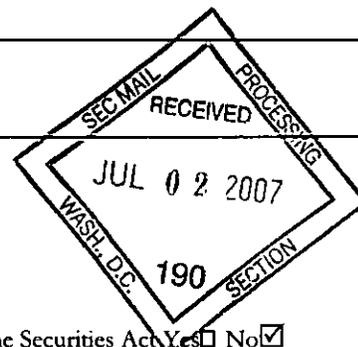
(IRS Employer Identification No.)

125 CambridgePark Drive, Cambridge, MA 02140

(Address of principal executive offices) (Zip Code)

(617) 349-4500

(Registrant's telephone number, including area code)



Securities Registered under Section 12(b) of the Exchange Act: None

Securities Registered under Section 12(g) of the Exchange Act: Common Stock, \$.001 par value

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of the voting common stock held by nonaffiliates of the registrant as of June 30, 2006 was approximately \$93,857,195.

The number of shares of the registrant's common stock outstanding as of March 1, 2007: 40,463,081 shares.

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## PART I.

### ITEM 1. BUSINESS

#### Background

Javelin Pharmaceuticals, Inc. is engaged in the research and development of products for the pain management market. Unless the context otherwise requires, all references in this report to "Javelin", "Company", "we", "us" or "our" include Javelin Pharmaceuticals, Inc., and any subsidiaries or other entities controlled by us.

Javelin was incorporated in July 2005 in the State of Delaware by Intrac, Inc., a Nevada corporation ("Intrac"), for the purpose of migrating the Intrac corporate entity to Delaware. The migratory merger became effective in September 2005. In December 2004, Innovative Drug Delivery Systems, Inc. ("IDDS"), then a private operating corporation, merged with Intrac, then a public reporting "shell" company, for the purpose of conducting the IDDS operations in a public entity. Intrac had been formed in September 2000 and had no active business operations between 2001 and December 2004. Following the Intrac-IDDS merger, the IDDS operations became the business of Intrac, and certain of the executive officers and directors of IDDS became our executive officers and directors. As a result of the migratory merger, IDDS became a wholly-owned subsidiary of Javelin. In July 2006, our common stock was listed on the American Stock Exchange. The shares of common stock described in this report give effect to the Intrac-IDDS merger and to the migratory merger.

#### Overview

We are a specialty pharmaceutical company that applies proprietary technologies to develop new products and improved formulations of existing drugs that target current unmet and underserved medical needs primarily in the pain management market. We are developing simple and user-friendly products, including new modes and routes of delivery for drugs optimized for relieving moderate-to-severe pain. In doing so, we intend to offer novel proprietary products that in some cases can be administered in a less invasive manner and generally should offer either improved safety or efficacy, or both, when compared to the currently available formulations on the market. In addition, the product choices currently available for the treatment of moderate-to-severe pain are limited in the doses that may be given due to side effects, including cardiovascular depression, tolerance and addiction, respiratory depression, constipation, sedation and general diminution of quality of life. Our product candidates are focused on treating a variety of pain disorders ranging from acute and episodic moderate-to-severe pain associated with breakthrough cancer pain, post-operative pain, post-trauma pain, such as orthopedic injury pain, procedural pain and burn pain. We believe that our products, assuming regulatory approvals, will offer the medical community and patients significant benefits and alternatives to the prescription pain medications available to pain sufferers today.

Our plan of clinical operations for the next 12 months involves conducting the necessary research and development to advance each of our three late stage product candidates, Dyloject™ (injectable diclofenac), PMI-150 (intranasal ketamine) and Rylomine™ (intranasal morphine), along the drug development process. The existing formulations of these parent drugs, including oral diclofenac, injectable ketamine, and oral and injectable morphine, are well-known prescription medications with well-documented profiles of safety, efficacy and cost-effectiveness.

Our development program is designed to support global product registration, although special emphasis is placed upon U.S. and European filings for drug approval and product registration. Currently, Dyloject™, PMI-150 and Rylomine™ have completed the Phase II product development stage based upon the U.S. regulatory classification. Over the coming year, development activity will focus on fulfilling the manufacturing requirements and generating the necessary preclinical and clinical data to support the submission packages outlined at our End-of-Phase II meetings at the U.S. Food and Drug Administration ("FDA") for Dyloject™ and Rylomine™ in the first half of 2006, and at our pre-Phase III FDA meeting for PMI-150 in January 2007.

All three of our product candidates are in late stage development as shown below:

Product candidate	Territory	Indication	Development stage
Dyloject™ (injectable diclofenac)	U.S. Europe	Post-operative pain Post-operative pain, anti-inflammatory	Phase III MAA Review
PMI-150 (intranasal ketamine)	U.S.	Acute moderate-to-severe pain	Completing registration studies
Rylomine™ (intranasal morphine)	U.S.	Acute moderate-to-severe pain	Phase III

Our most advanced product candidate in Europe is Dyloject™. In July 2005, we announced that we had met our primary endpoint in the pivotal European Phase II/III study for Dyloject™. In September 2005, at the European Society of Regional Anesthesia and Pain Therapy annual meeting, we presented comprehensive results of this randomized, double-blind, placebo- and comparator-controlled Phase II/III pivotal clinical trial comparing the safety, efficacy and therapeutic equivalency of Dyloject™ to Voltarol®. The Marketing Authorization Application (“MAA”) submission for approval to sell Dyloject™ in Europe was filed in September 2005, and was accepted for review in October 2005. The MAA review process has typically taken between 12 to 18 months for marketing authorization, rejection or approval subject to completion of additional requirements imposed on the applicant by the regulatory agency at the time of review completion. There can be no assurance as to whether or when such application will be approved. Should we receive approval for Dyloject™, we will also continue to take the necessary steps to facilitate a product launch, including distribution, marketing and sales activities beginning in the U.K. with the intent to further distribute, market and sell the product throughout certain European countries.

In January 2006, we announced that we had met our primary endpoint of a linear dose response for pain relief over six hours in a Phase IIb U.S. study of Dyloject™. The preliminary results of this randomized, double-blind, placebo- and comparator-controlled clinical trial comparing the safety and efficacy of Dyloject™ to IV ketorolac demonstrated that patients with moderate-to-severe pain after oral surgery who received Dyloject™ or IV ketorolac experienced statistically significant pain relief over six hours compared to patients who received a placebo. In addition, approximately five minutes after intravenous injection, Dyloject™ demonstrated superior onset of pain relief compared to ketorolac as measured by statistically significant reductions in pain intensity and pain relief using both the VAS and categorical scales. Moreover, in September 2006, we announced at “Europe Against Pain,” the annual meeting of the European federation of chapters of the International Association for the Study of Pain, that the minimally effective dose of Dyloject™ in this study was 3.75mg, which is an unexpectedly low dose and novel finding. To achieve analgesia with lower doses of injectable diclofenac than was previously understood as necessary offers the potential to reduce dose-related adverse affects with substantially equivalent analgesia. In June 2006, we commenced enrolling patients in a larger post-operative pain study in fulfillment of completing two Phase III studies for Dyloject™ necessary for filing the New Drug Application (“NDA”) for the U.S. program.

In 2005, we completed the PMI-150 formulation and device bioequivalency programs and initiated additional Phase II studies. We met with the FDA in January 2007 to finalize the development plan for this product candidate. At this meeting, the FDA indicated that no additional clinical efficacy trials would be needed prior to filing an initial NDA. Therefore, we intend to undertake four remaining pharmacokinetic studies and then to file an NDA for this product candidate as an emergency analgesic for military and civilian use in 2008. With respect to other potential applications for this product, we are preparing to commence Phase III clinical trials. We are also continuing internal deliberations regarding the development of our PMI-150 product candidate in Europe.

In October 2005, we announced that we had met our primary endpoint of a linear dose response for pain relief over four hours in a Phase IIb study of Rylomine™. In February 2006, at the American Academy of Pain Medicine annual meeting, we presented comprehensive results of this randomized, double-blind, placebo- and comparator-controlled clinical trial comparing the safety and efficacy of Rylomine™ to IV morphine. This study demonstrated that patients with moderate-to-severe pain after orthopedic surgery who received Rylomine™ or intravenous morphine experienced statistically significant pain relief over four hours compared to patients who received a placebo. In April 2006, we announced that we held our End-of-Phase II meeting with the FDA and in May 2006, we initiated the U.S. Rylomine™ Phase III clinical program. We are also focused on seeking regulatory and scientific advice from French regulatory experts and the European Agency for Evaluation of Medicinal Products. The results of the clinical trials along with feedback from the regulatory agencies will determine the timing, extent and cost of the European Rylomine™ development program and product filings.

Through December 31, 2006, we had invested approximately \$57.2 million in research and development activities. The proprietary technology used to develop our product candidates is protected by patents filed and/or approved both in the United States and in other countries throughout the world. We have licensed the worldwide exclusive rights to develop and commercialize the proprietary formulations of these product candidates. Since inception, we have been awarded over \$5.8 million in competitive and peer-reviewed government funding, including contracts from the U.S. Department of Defense and grants from the National Institutes of Health/National Cancer Institute.

### **Pain Pharmaceuticals Market Overview**

The value of the global pharmaceutical market for pain relief was approximately \$23 billion in 2004 ([www.arrowheadpublishers.com/PainTherapeutics.html](http://www.arrowheadpublishers.com/PainTherapeutics.html)). Two-thirds of the dollar volume of the U.S. prescription pain medication market is for drugs used to treat chronic pain, and one-third is for drugs used for indications associated with acute pain. Our products are designed to fulfill unmet and underserved medical needs for a number of moderate-to-severe pain indications, including breakthrough cancer pain, post-operative pain, breakthrough lower back pain, orthopedic injury pain, and burn pain. Despite advances in medicine and the development of new prescription pain medications, we believe that treatment for these indications remains a critical area of unmet and underserved medical need.

## Market Opportunity

Despite advances in medicine and the development of new drugs, pain relief remains a critical area of unmet and underserved medical need. Increasingly, patients, advocacy groups, and the media are highlighting the shortcomings of pain management. The Joint Commission for the Accreditation of Healthcare Organizations has recently introduced new standards for pain assessment and control, but the methods to fulfill these standards are still suboptimal, in large part due to their slow onset and side effects. Commercially available oral pain medications generally take 15-20 minutes and sometimes as long as 40 minutes to provide clinically meaningful pain relief. Undertreatment or overtreatment often results from limitations upon optimal dosing of currently available drugs to meet the patient's analgesic requirements, due to side effects of these drugs and their current delivery methods. Further, presently available drugs can be partially effective or simply ineffective. Other shortcomings of existing pain drugs include poor side effect profiles and requirements for invasive, resource-intensive routes of administration such as an intravenous infusion.

We are developing differentiated pain control products that provide the flexibility and versatility required to adequately address the limitations of existing prescription pain pharmaceuticals. First, all three of our product candidates appear to work faster than the oral formulations of the currently available prescription pain products. These product formulations provide rapid relief of moderate-to-severe pain within minutes according to our clinical results (within 5 minutes for PMI-150 and within 10 minutes for Rylomine). For Dyloject, in particular, we have found an unprecedented speed of onset of pain relief (within five minutes) compared with currently marketed injectable anti-inflammatory drugs.

Second, our PMI-150 and Rylomine™ product candidates address patient and provider preferences for self-medication and serve as a less invasive route of administration. Both product candidates have IV-like pharmacokinetics without the invasive nature of IV administration or the need for costly and cumbersome patient controlled analgesia ("PCA") devices. These product candidates present a significant opportunity for drug therapy both inside the hospital setting and in other medically supervised settings. Their economic benefit is compelling as the nasal route of administration eliminates the need for personnel and equipment necessary to establish an IV line. In addition, a non-invasive route of delivery reduces the incidence of needle-stick injuries and the potential for transmission of blood-borne viruses. Finally, the ability to self-regulate provides an important benefit of control to the patient and avoids doses that are higher than necessary to achieve safe and effective management of pain without the side effects associated with such higher doses.

Third, our Dyloject and PMI-150 product candidates provide alternatives to the use of opioids such as morphine for treating moderate-to-severe pain. Opioid administration to trauma patients must be undertaken with great caution, vigilance and repeated titration of very small doses due to their recognized risks of lowering blood pressure and causing respiratory depression. PMI-150 has been used off-label to treat trauma pain, as it does not have the same potentially lethal, dose-limiting side effects as an opioid. The typical treatment of breakthrough pain requires a combination of various opioids. When used in combination with opioids, ketamine has been reported to reduce the dependence on opioids, thereby reducing the requirement for narcotics, and enhancing the patient's overall quality of life.

Dyloject™ has the potential to provide an attractive alternative to opioids for the treatment of post-operative pain. Our most significant U.S. competitor in the injectable nonsteroidal anti-inflammatory drugs ("NSAID") category is ketorolac tromethamine. In January 2006, we announced the results of a Phase IIb U.S. study in which Dyloject™ demonstrated superior onset of action compared to ketorolac, five minutes after intravenous injection. When first launched, this drug had significant sales prior to the FDA imposing a black box warning limiting the combined duration of IV plus oral use of Toradol® to five days because of the risk of serious adverse events. Oral diclofenac can be used safely in excess of five days and has a considerably superior safety profile. Our Dyloject™ product candidate would be the first injectable version of diclofenac to be marketed in the U.S. We believe that Europe presents a meaningful opportunity for Dyloject™ as well because injectable Voltarol® (diclofenac sodium) has significant drawbacks, including the need to freshly prepare, buffer and dilute at the pharmacy and infuse to the patient slowly over 30 minutes.

Oral diclofenac is a leading prescribed product in the post-operative pain category. Dyloject would provide the medical healthcare provider, for the first time, with an injectable version of this drug for use in the immediate post-operative, in-hospital period. We anticipate that the consistency of parent drug and the drug's dosage and administration regimen will allow for easy transition from injectable to oral diclofenac when post-operative patients are able to resume oral intake, thereby lowering the barrier to entry and driving product adoption.

## Pain Indications

The following describes the five key pain indications targeted by us.

### — *Breakthrough Cancer Pain*

The prevalence of cancer pain is growing due to the progressive aging of the general population and further increases in cancer survival rates as a result of new therapies and treatments. Cancer pain represents the sum of continuous or baseline pain, for which round-the-clock regimens of long-acting analgesics are generally recommended, plus intermittent or breakthrough pain, for which the current standard of care is to administer as-needed, immediate-release oral opioids ([www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.18803](http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.18803)). Breakthrough cancer pain is characterized by episodes of acute, moderate-to-severe pain that suddenly flare up and overcome a standing, by-the-clock pain

management regimen ([www.whocancerpain.wisc.edu/eng/17\\_4/Interview](http://www.whocancerpain.wisc.edu/eng/17_4/Interview)). This type of pain is particularly difficult to treat due to its severity, rapid onset, and the often unpredictable nature of its occurrence. On average, patients suffering from breakthrough cancer pain experience one to five breakthrough episodes per day. Based upon careful estimates of the prevalence of cancer breakthrough pain conducted both within the U.S. and internationally ([www.whocancerpain.wisc.edu/eng/17\\_4/Research](http://www.whocancerpain.wisc.edu/eng/17_4/Research)), we estimate that about two-thirds of the approximately 785,000 patients in the U.S. suffering from moderate-to-severe cancer pain require treatment for breakthrough pain. We believe, based upon the properties that our product candidates have displayed in our clinical trials to date, that one or more of them might provide a faster-acting and more effective alternative treatment for breakthrough cancer pain.

#### **— Post-Operative Pain**

Post-operative pain is typically attributable to acute, moderate-to-severe pain and is the direct result of a surgical procedure and the resulting inflammation associated with the trauma of surgery. Each year in the U.S., 15 million surgeries are performed that require opioid therapy. Post-operative pain following minor surgical procedures is usually treated with oral or parenteral NSAIDs or a weak oral opioid. More invasive surgical procedures require hospitalization for monitoring and management of post-operative pain. Intravenous patient-controlled analgesia ("PCA") with opioids is the therapy of choice for treating this latter patient population prior to discharge from the hospital. PCA allows a patient to receive drugs on demand by using an infusion pump that is programmed by the physician to intermittently administer a single dose of a drug, typically morphine or a similar opioid, when the patient pushes a button. The addition of parenteral or oral NSAIDs to this regimen is gaining broader use as NSAIDs have been demonstrated to decrease the requirement for opioids. We believe that one or more of our product candidates might be effective for the management of pain following minor surgical procedures and offer a readily acceptable alternative to IV PCA for the management of moderate-to-severe pain and breakthrough pain following major surgical procedures.

#### **— Breakthrough Back Pain**

Lower back pain is the most common medical complaint in developed countries. Thus, the potential patient population is extremely large, and while a host of physiotherapy, nerve block and surgical approaches are available, analgesics are the mainstay of most therapeutic treatment programs. According to the National Institutes of Health, Americans spend approximately \$50 million each year on lower back pain ([www.ninds.nih.gov/disorders/backpain/detail\\_backpain.htm](http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm)), the most common cause of job-related disability and a leading contributor to missed work. The most severe episodes require the use of opioids. We believe that one or more of our product candidates might effectively treat the subset of patients suffering from breakthrough episodes of lower back pain whose cases are severe enough to be activity-limiting.

#### **— Orthopedic Injury**

Treatment of fractures can involve the realignment of bones, a procedure referred to as reduction. Although fractures and dislocations are generally due to minor injuries, the time leading up to and during reduction of a fracture or the correction of a dislocation is often associated with acute, moderate-to-severe pain. According to the National Center for Health Statistics' Annual Health Survey published in 2001, there were approximately 15 million emergency department visits due to fractures or dislocations in the U.S. annually from 1992-1999. ([www.cdc.gov/nchs/data/series/sr\\_13/sr13\\_150.pdf](http://www.cdc.gov/nchs/data/series/sr_13/sr13_150.pdf)). We believe that emergency departments have an economic incentive to use any therapy that can speed patient discharge from the hospital and avoid expenses associated with administration of intravenous drugs. We also believe that one or more of our product candidates might satisfy the underserved medical need for agents that are fast-acting, safe, and easily titrated to treat moderate-to-severe pain associated with orthopedic injury in the emergency department setting.

#### **— Burn Pain**

According to the American Burn Association, there are over one million burn injuries each year in the U.S., of which 700,000 present to emergency rooms and 45,000 require hospitalization ([www.ameriburn.org/pub/BurnIncidenceFactSheet.htm](http://www.ameriburn.org/pub/BurnIncidenceFactSheet.htm)). Burn pain in the latter group is typically immediate and of moderate-to-severe intensity as a result of injuries sustained after thermal, chemical or electrical trauma to skin and deeper tissue, as well as the removal or reapplication of dressings applied to the initial burn. Burn pain is often more challenging to control than post-operative pain and is currently treated with potent intravenous opioids, oral opioids, and other oral analgesics. Pain associated with burn trauma continues to impair the lives of burn victims long after the initial injury and hospitalization. The published research on pain in this population is much less extensive than for post-operative or cancer pain, and we believe the burn pain patient population to be largely underserved. We believe that one or more of our product candidates might be effective for the management of pain following in-patient burn treatments, as well as for treating various forms of procedural pain, including wound care treatments and dressing reapplications.

#### **Strategy**

Our goal is to become a successful specialty pharmaceutical company by focusing our efforts on developing new prescription pain medications that are simple, user friendly and cost-effective for the potential future treatment of patients with underserved pain management needs. Key elements of our strategy are:

- **Focus on unmet and underserved medical needs in the prescription pain medication market.** Despite advances in medicine and the development of new drugs, pain relief remains a critical area of unmet and underserved medical need. Increasingly, patients, advocacy groups and the media are highlighting the shortcomings of pain management. We will continue to focus on developing and commercializing differentiated pain control products that provide the flexibility and versatility required to adequately address the limitations of existing prescription pain drugs.
- **Efficiently select product candidates to minimize risk and maximize opportunity.** We will continue to use in-house experience and capabilities in product development, business development, regulatory affairs, risk management and portfolio management to build and maintain an attractive product portfolio and candidate pipeline.
- **Develop new products with reduced clinical and regulatory risk.** Following the specialty pharmaceutical business model, we will seek to develop branded pharmaceuticals with novel formulations, routes of administration, methods and modes of delivery and new indications from existing approved drugs with established safety profiles.
- **Retain sales and marketing rights to product candidates through late stage development.** We currently retain U.S. and worldwide marketing and distribution rights for our products. We may retain marketing rights for narrow distribution channels in the U.S. and license out broader distribution channels and non U.S. rights.

## Products

We are developing differentiated pain control products that provide the flexibility and versatility required to adequately address the limitations of existing prescription pain pharmaceuticals. The current pipeline includes three lead product candidates, each of which is protected by different intellectual property and is based on different technology. We selected these product candidates based on our belief that each offered significantly lower clinical, regulatory, and commercial risk profiles as compared to new chemical entities.

### Dyloject™ (diclofenac sodium injectable)

*Background.* After operations or trauma, injured tissue becomes inflamed. This inflammation is painful. Common drugs that reduce inflammation fall into two broad classes. First are the steroids (short for corticosteroids, such as cortisone). These are potent anti-inflammatory drugs but their use even for short intervals carries substantial risks such as weakening of the bones or a tendency towards infections. Thus, corticosteroids are not routinely used after operations. The second class comprises nonsteroidal anti-inflammatory drugs (NSAIDs), which include prescription drugs for the treatment of moderate-to-severe pain, as well as the more common and numerous over-the-counter prescription drugs for the treatment of mild-to-moderate pain, such as aspirin. NSAIDs are widely used for all types of pain, but relatively few can treat the moderate-to-severe pain typically experienced following operations. NSAIDs reduce pain and inflammation through several mechanisms, principal among which is their ability to interfere with the enzyme class known as cyclo-oxygenases. This enzyme acts upon certain fatty acids made by the body to generate pain-mediating substances known as prostaglandins. Inhibition of the cyclo-oxygenases by NSAIDs reduces prostaglandin levels decreasing inflammation and thus reducing the pain associated with the inflammatory response. Diclofenac is a prescription NSAID that is widely prescribed to treat post-operative pain due to its combination of effectiveness and tolerability.

Currently available formulations of the popular drug diclofenac are poorly soluble in water. We have successfully improved the solubility of diclofenac by the addition of a doughnut-shaped molecule that has the technical name hydroxypropyl-beta-cyclodextrin (HPβCD). Diclofenac and HPβCD can be formulated to easily dissolve in water. This resultant product is more amenable for injection into a muscle or a vein, where the solubilized material is able to directly enter the bloodstream. HPβCD is one example of a broader family of ring-shaped sugar molecules called cyclodextrins. Cyclodextrins have been used to improve the solubility of many hard-to-dissolve drugs. There are many types of cyclodextrins and most are toxic. Only modified cyclodextrins such as HPβCD are regarded as safe for injection. Our HPβCD is used in higher concentrations in the FDA-approved injectable antifungal drug, Sporanox® (itraconazole).

NSAIDs offer several advantages over opioids for the management of post-operative pain. NSAIDs have limited effects on the central nervous system, do not depress respiration and are non-sedating. This latter attribute is of special importance in short-stay or ambulatory surgery because NSAIDs can provide analgesia without delaying patient discharge from the hospital or outpatient setting. In addition, NSAIDs are also useful in patients who for any reason are unable to take opioids. About a decade ago it became clear that there are at least two forms of the enzyme cyclo-oxygenase (abbreviated "COX"). COX 1 plays a role in protecting the stomach from forming ulcers, and also for allowing blood to clot in the first minute after a cut or incision. COX 2 becomes active after inflammation or trauma, and also is important for normal kidney function. The recognition that COX 1 and COX 2 serve different functions led to the development and wide use of drugs that selectively inhibited COX 2 and not COX 1, based upon the potential for such drugs to reduce pain and inflammation with fewer stomach ulcers, and less effect upon blood clotting, than the nonselective NSAIDs. However, in the past several years it has also become clear that some COX 2 inhibitors (also called "coxibs") interfere with the health of blood vessels in the heart and those going to the brain, and increase the risk of heart attack or stroke. The expanding concerns about heart attacks and strokes associated with long-term use of COX 2 inhibitors and, most recently, naproxen do not necessarily apply to the short-term, perioperative administration of these compounds for acute pain. Clinical trials to date have not demonstrated increased cardiovascular and cerebrovascular risk associated with the short-term

use of COX 2 inhibitors and naproxen to treat acute postsurgical pain. On the other hand, clinician's global concerns including fears of litigation associated with any medical complications after prescribing oral or injectable COX 2 inhibitors may reduce the current and projected market share of COX 2 inhibitors for the treatment of acute pain. Diclofenac is not considered to be a selective COX 2 inhibitor because it inhibits COX 1 and COX 2 alike.

There still exists an underserved medical need for a safe and effective injectable NSAID in the hospital setting. For example, ketorolac tromethamine is an injectable NSAID that had significant sales prior to the FDA's imposing a black box warning limiting the combined duration of IV plus oral use to five days because of the risk of serious adverse events. Oral diclofenac can be used safely in excess of five days and has a safety profile, considered superior to oral ketorolac. Diclofenac is currently approved for use in the U.S. in a variety of oral formulations as well as a topical and ophthalmic formulation. An injectable formulation of diclofenac is commercially available in Europe, but has significant drawbacks, including the need to buffer and dilute it at the pharmacy and a lengthy infusion period (over thirty minutes). The development of injectable formulations of diclofenac has been limited by the drug's poor solubility. We believe that the proprietary formulation of injectable diclofenac that we are developing has the potential to overcome these issues and to provide an effective and safe treatment of moderate-to-severe acute pain.

*Clinical Results.* Dyloject™ is in development in the U.S. for the treatment of post-operative pain and in Europe for the treatment of acute forms of pain, including renal colic, exacerbations of osteo- and rheumatoid arthritis, acute back pain, acute gout, acute trauma, pain associated with fractures in addition to post-operative pain.

Initial studies of Dyloject, when administered by intravenous or intramuscular injection, have demonstrated its safety along with a safe rapid onset of action. Dyloject has also demonstrated bioequivalence to Voltarol®. Published results from a Phase II 269-patient randomized, placebo-controlled, double-blind clinical trial demonstrated that Dyloject provides a rapid drop in post-operative pain intensity. At all dosage levels tested, Dyloject provided statistically significant post-operative pain relief through 6 hours ( $p < 0.05$ ) and was safe and well-tolerated by patients. The results of this clinical study were published in 2000 in the European Journal of Clinical Pharmacology.

In October 2003, we completed a randomized, four-way cross-over Phase I trial comparing the pharmacokinetics, bioequivalence and safety of Dyloject™ to Voltarol®. Dyloject™ was bioequivalent to Voltarol® regardless of intravenous infusion time as defined and required by the Medicines and Health Products Regulatory Agency ("MHRA").

In March 2004, we completed a randomized, four-way cross-over Phase I clinical study comparing the pharmacokinetic, bioequivalence and safety of Dyloject™ to Voltarol® when administered intravenously and intramuscularly. Dyloject™ was found to be bioequivalent to Voltarol® regardless of the route of administration and was safe and well tolerated.

In July 2004, we initiated a randomized, double-blind, placebo- and comparator-controlled Phase II/III pivotal clinical trial comparing the safety, efficacy and therapeutic equivalency of Dyloject™ to Voltarol®. In July 2005, we announced that we had met our primary endpoint in the pivotal European Phase II/III study. In September 2005, at the European Society of Regional Anesthesia and Pain Therapy (ESRA) annual meeting, we presented the final results of this randomized, double-blind, placebo- and comparator-controlled Phase II/III pivotal clinical trial comparing the safety, efficacy and therapeutic equivalency of Dyloject™ to Voltarol®. An MAA (marketing authorization application) submission for approval to sell this product in Europe was filed in September 2005 and the MHRA granted allowance in October 2005. The review and approval process typically takes between 12 to 18 months for marketing authorization, rejection, or approval subject to completion of additional requirements imposed on the company by the regulatory agency at the time of review completion. Should we receive approval for Dyloject™, we will also continue to take the necessary steps to facilitate a product launch, including distribution, marketing and sales activities beginning in the U.K. with the intent to further distribute, market and sell the product throughout certain European countries.

In January 2006, we announced that we had met our primary endpoint of a linear dose response for pain relief over six hours in a Phase IIb U.S. study of Dyloject. The preliminary results of this randomized, double-blind, placebo- and comparator-controlled clinical trial comparing the safety and efficacy of Dyloject to IV ketorolac demonstrated that patients with moderate-to-severe pain after oral surgery who received Dyloject or IV ketorolac experienced statistically significant ( $p < 0.05$ ) pain relief over six hours compared to patients who received a placebo. In addition, approximately five minutes after intravenous injection, Dyloject demonstrated superior onset of pain relief compared to ketorolac as measured by statistically significant ( $p < 0.05$ ) reductions in pain intensity and pain relief using both the VAS and categorical scales. Moreover, in September 2006, we announced at "Europe Against Pain," the annual meeting of the European federation of chapters of the International Association for the Study of Pain, that the minimally effective dose of Dyloject™ in this study was 3.75mg, which is an unexpectedly low dose and novel finding. To achieve analgesia with lower doses of injectable diclofenac than was previously understood as necessary offers the potential to reduce dose-related adverse affects with substantially equivalent analgesia. In June 2006, we commenced enrolling patients in a larger post-operative pain study in fulfillment of completing two Phase III studies for Dyloject™ necessary for filing the NDA for the U.S. program.

## **PMI-150 (intranasal ketamine)**

*Background.* PMI-150, a proprietary nasal formulation of ketamine, is currently under development by us for treatment of acute moderate-to-severe pain, including breakthrough pain. Ketamine, a non-opiate, is an N-methyl-D-aspartate ("NMDA") receptor antagonist that has been in clinical use for over 30 years as a general anesthetic. Since its approval by the FDA, ketamine has been safely used as an anesthetic in tens of thousands of patients. NMDA receptors are located in the central nervous system and play a role in the perception of acute and chronic pain as well as in the development of analgesic tolerance to opioids. Ketamine blocks NMDA receptors and therefore is a logical drug candidate for use as an analgesic for syndromes associated with acute pain, as well as breakthrough pain. Ketamine, at lower doses than that approved for use as an anesthetic, has been reported in the medical literature to be an effective analgesic in settings such as post-operatively, during medical procedures, and for neuropathic pain.

As reported in recent medical literature, the use of ketamine as an analgesic, while not yet approved by the FDA, is gaining clinician acceptance as a result of its effectiveness and minimal impact on cardiovascular and respiratory functions. Since ketamine is not approved for use as an analgesic, physicians have resorted to using the drug off-label. We believe that an FDA-approved formulation of ketamine for the treatment of moderate-to-severe pain will provide physicians with an accepted and regulated alternative to off-label use. In addition, in 1998, ketamine was scheduled by the U.S. Drug Enforcement Administration (the "DEA") as a Schedule III controlled substance. We believe this will only improve the prospects of our intended use of ketamine, as the scheduling of ketamine by the DEA provides additional protection with respect to controlling distribution, prescribing patterns and disposal, thereby reducing the potential for misuse.

*Clinical Results.* PMI-150 is in development in the U.S. for the treatment of acute moderate-to-severe pain and breakthrough pain. We believe that PMI-150 is optimized for use as a pain medication and potentially offers a safe, non-opioid alternative for the treatment of moderate-to-severe pain.

Previous randomized, double-blinded, placebo-controlled Phase II clinical studies have demonstrated statistically significant ( $p < 0.05$ ) relief of moderate-to-severe post-operative and breakthrough pain. PMI-150 was fast-acting, with statistically significant ( $p < 0.05$ ) pain relief occurring as early as 4 minutes post administration of PMI-150. PMI-150 also appeared to be safe and well-tolerated by patients. These results were presented at the American Society for Clinical Pharmacology and Therapeutics in Atlanta, Georgia in April 2002 and the American Society of Clinical Oncology in Orlando, Florida in May 2002.

In May 2003, following the presentation of clinical data at the plenary session of the Advanced Technology Application for Combat Casualty Care conference in Orlando, Florida, the U.S. Department of Defense awarded an approximately \$4.3 million funding extension to IDDS to aid in the development of PMI-150. This award is based on the need of the military for a fast-acting, non-invasive, and non-sedating alternative to the intravenous and oral medications commonly used for treatment of combat-related injuries, such as burns, bullet wounds and blunt trauma.

In June 2004, we had an End-of-Phase II meeting with representatives of the FDA. The purpose of the meeting was to review the intended clinical use and the proposed product development plan for PMI-150. The FDA provided guidance and defined the requirements for NDA submission. In 2005, we completed the PMI-150 formulation and device bioequivalency programs and initiated additional Phase II studies. We met with the FDA in January 2007 to finalize the development plan for this product candidate. At this meeting, the FDA indicated that no additional clinical efficacy trials would be needed prior to filing an initial NDA. Therefore, we intend to undertake four remaining pharmacokinetic studies and then to file an NDA for this product candidate as an emergency analgesic for military and civilian use in 2008. With respect to other potential applications for this product, we are preparing to commence Phase III clinical trials. We are also performing internal deliberations regarding the development of our PMI-150 product candidate in Europe.

## **Rylomine™ (intranasal morphine)**

*Background.* Rylomine™ is in development in the U.S. and Europe for the treatment of acute moderate-to-severe pain and breakthrough pain. Breakthrough pain is acute pain that overcomes or breaks through a patient's fixed, by-the-clock doses of pain medicine. Morphine, the active pharmaceutical ingredient in Rylomine™, is the analgesic standard to which all other opioids are usually compared, and has potent effects upon the mu-opioid receptor that is found in many nerve cells with pain pathways. When morphine binds to this receptor, it interferes with the transmission of pain signals from nerve endings and across nerve pathways to the spinal cord and brain. The power of morphine to reduce the level of physical distress places it among the most important naturally occurring compounds. Morphine is a strong analgesic used for the relief of moderate-to-severe acute and chronic pain, pre-operative sedation, and as a supplement to anesthesia. It is the drug of choice for treating moderate-to-severe pain associated with, in part, surgical operations, myocardial infarction and cancer.

*ChiSys™ Delivery Platform.* We have licensed a proprietary drug delivery technology that allows us to nasally deliver and to achieve therapeutic blood levels of morphine in a predictable fashion that was previously unattainable when administered through the nasal route. The key to this technology is ChiSys™, a naturally occurring carbohydrate polymer that, while pharmaceutically inert by itself, enhances the absorption of compounds across mucosal membranes such as those of the nasal cavity, and thereby provides the potential to deliver drugs through such routes. This enhancement of drug delivery is particularly important for compounds such as morphine that are poorly absorbed across

mucosal barriers, in particular, the nasal membrane. The contribution of ChiSys™ to enhancing mucosal drug absorption is reported to be due to several factors, including its potent mucoadhesive property, which prevents drug washout.

Conventional oral formulations of morphine do not provide rapid relief of pain in many patients. Aside from its slow and variable onset of action, oral morphine demonstrates considerable patient-to-patient variability in absorption. Clinicians therefore must rely on injection of morphine into a muscle or a vein to assure rapid and effective pain relief. Administration of injectable morphine requires professional assistance or hospitalization. Therefore, alternative formulations of morphine that are easy to administer by a patient or caregiver, and that deliver rapid onset of action with clinically meaningful blood levels of active drug, would provide significant medical benefit. We believe that Rylomine represents such an alternative nasal formulation that combines patient convenience, ease of use, and cost-effectiveness with rapid onset of pain relief and well-accepted potency equivalent to injectable delivery routes.

Previous single and multiple-dose Phase I clinical studies of Rylomine have demonstrated similar pharmacokinetics to intravenous morphine. Rylomine is rapidly absorbed to produce blood levels of morphine typically associated with analgesic effectiveness. These data were presented at the 2002 International Association for the Study of Pain 10th World Congress on Pain, in San Diego, CA.

In December 2002, we completed a large randomized, placebo- and comparator-controlled, double-blind, phase II trial evaluating the safety and effectiveness of Rylomine in 225 patients suffering from moderate-to-severe post-operative pain. Rylomine provided statistically superior pain relief as compared to a placebo ( $p < 0.05$ ), with appreciable pain relief occurring five to ten minutes following nasal administration. Rylomine™ delivered a statistically similar onset of action and total pain relief outcome as compared to intravenous morphine infused over 10 minutes. Rylomine™ also demonstrated a lower side effect profile and faster onset of action compared to oral morphine.

In October 2005, we announced that we had met our primary endpoint of a linear dose response for pain relief over four hours in a Phase IIb study of Rylomine. In February 2006, at the American Academy of Pain Medicine annual meeting, and in May 2006 at the American Pain Society (APS) annual meeting, we presented the final results of this randomized, double-blind, placebo- and comparator-controlled clinical trial comparing the safety and efficacy of Rylomine to IV morphine. Patients with moderate-to-severe pain after orthopedic surgery who received Rylomine 15 mg or 30 mg or intravenous morphine 7.5 mg experienced statistically significant ( $p < 0.01$ ) pain relief over four hours compared to patients who received a placebo. One nasal spray of Rylomine 7.5 mg was determined to be the minimally effective dose and equivalent to a 5 mg bolus IV injection of morphine. In this study, Rylomine™ 7.5 mg and 15 mg were effective at relieving pain over 24 hours with the higher dose showing superior efficacy and the lower dose showing better tolerability. There were no serious adverse events and most side effects were reported as mild to moderate in intensity. General side effects were dose related and typical of morphine administration. Local adverse events were typical of nasally administered drugs and included bad taste, nasal congestion, nasal discomfort, throat irritation, sneezing and rhinorrhoea.

In April 2006, we announced that we held our End-of-Phase II meeting with the FDA and in May 2006 we initiated the U.S. Rylomine Phase III clinical program. We are also focused on seeking regulatory and scientific advice from French regulatory experts and the European Agency for Evaluation of Medicinal Products (the "EMA"). The results of the clinical trials along with feedback from the regulatory agencies will determine the timing, extent and cost of the European Rylomine development program and product filings.

### **Competitive Grants**

We have received the following grants that provide both financial and development support for several of our clinical programs.

#### **— U.S. Department of Defense**

The U.S. Department of Defense has awarded the Company a total of approximately \$5.5 million in contracts and grants to develop PMI-150 for the treatment of acute moderate-to-severe pain in military personnel and for mass casualty management. These contracts reimburse the Company for expenses associated with some aspects of the non-clinical, clinical and manufacturing sub-projects required to support an NDA submission.

### **Strategic Agreements**

#### **— Shimoda Agreement**

In December 2001, we entered into a license agreement with Shimoda Biotech, Ltd. and its wholly-owned subsidiaries, Farmarc N.A.N.V. (Netherlands Antilles) and Farmarc Netherlands B.V. (collectively, "Shimoda") pursuant to which we received certain worldwide, exclusive rights to develop and commercialize products related to a proprietary formulation of the injectable delivery of diclofenac. Shimoda's rights to the formulation were originally licensed from Janssen Pharmaceutica Products, L.P. Under the terms of this agreement, we agreed to use commercially reasonable efforts to bring to market products that use the technology we licensed from Shimoda, continue active marketing efforts for those products, and comply with the commercialization timelines imposed on Shimoda. We are currently in compliance with the agreement and have positive relations with our license partners. Shimoda agreed that it will not grant to any third party any right or license under any of Shimoda's intellectual property rights involving the use of any cyclodextrin product related to pain management, anesthesia or

sedation without first offering us the right on the same terms and conditions. Under the license agreement, we are also obligated to pay an aggregate of \$6.0 million upon the occurrence of specified developmental milestones, which include the filing of an NDA with the FDA for Dyloject™, the approval of an NDA by the FDA and the first commercial sale of a licensed product, and pay a royalty based upon our and our sublicensees' sales of products. In December 2005, the agreement was amended to include allowance of an MAA by the MHRA, submission of an NDA to the FDA, approval of an NDA by the FDA and one year following the date of first sale of a licensed product. In May 2006, the agreement was further amended to provide that we will be considered compliant with the agreement even if we do not launch a commercial product by December 14, 2007, provided that we diligently continue to pursue regulatory approval as of that date. As of December 31, 2006, we had paid Shimoda an aggregate of \$2.1 million in cash since the inception of this agreement. Under this agreement, the timing of the remaining milestones is dependent upon factors that are beyond our control, including our ability to recruit patients, the outcome of future clinical trials and any requirements imposed on our clinical trials by the FDA. If the FDA imposes more stringent requirements on our clinical trials, the length and number of such trials may be increased resulting in additional research and development expenses. We are obligated to pay Shimoda, on a country-by-country basis, a royalty on the sales, net of various customary cash discounts, attributable to these products.

#### **— West Pharmaceutical Agreements**

In August 2000, IDDS entered into a license agreement, which was amended in October 2001 and October 2003, with West Pharmaceutical under which IDDS acquired a worldwide, exclusive right to develop and commercialize intranasal morphine under patents held by West Pharmaceutical for the transmucosal delivery of morphine to humans and animals for the treatment of pain. The licensed patent portfolio from West Pharmaceutical provides U.S. protection until 2014 and worldwide protection through 2016. The term of the license remains in effect until the last to expire of the Licensed Patents (as defined in the license agreement). We believe that IDDS' recently filed patent applications, if approved, will significantly expand the life of these patents. In the future, we may be required to pay West Pharmaceutical an aggregate of up to \$5.0 million for research and development milestones if certain defined events occur, which include the first filing of a marketing authorization application with a regulatory agency, first approval of a marketing authorization application and the first commercial sale of a licensed product. As of December 31, 2006, we had paid West an aggregate of \$5.6 million in cash since the inception of this agreement. The timing of the remaining milestones is dependent upon factors that are beyond our control, including our ability to recruit patients, the outcome of future clinical trials and any requirements imposed on our clinical trials by regulatory agencies. If regulatory agencies impose more stringent requirements on our clinical trials, the length and number of such trials may be increased resulting in additional research and development expenses. The Company is obligated to pay West Pharmaceutical a royalty on the sales, net of various customary cash discounts, attributable to intranasal morphine.

In February 2005, West Pharmaceutical sold a substantial majority interest in its drug delivery business to Archimedes Pharma Limited ("Archimedes"), a new company formed by Warburg Pincus Private Equity VIII and Warburg Pincus International Partners. As part of the sale, West Pharmaceutical assigned the IDDS License Agreement and related agreements to Archimedes, and Archimedes assumed all of West Pharmaceutical's obligations thereunder.

In February 2006, we settled a litigation with West Pharmaceutical regarding its assignment of the IDDS License Agreements to Archimedes. Subsequently, on March 1, 2006, West paid us approximately \$600,000 to resolve all claims, and the parties exchanged mutual releases.

#### **— Ketamine License**

In September 2000, IDDS assumed a license agreement with Dr. Stuart Weg upon the closing of its merger with Pain Management, Inc., another specialty pharmaceutical company. The license grants IDDS the exclusive, worldwide rights for the intellectual property surrounding intranasal ketamine. The term of the license agreement remains in effect until the last to expire of the patent rights. Under the license agreement with Dr. Weg, we are obligated to make aggregate milestone payments of approximately \$1.6 million to Dr. Weg, Herbert Brotspies and Calgar & Associates. As of December 31, 2006, we had paid Dr. Weg, Mr. Brotspies and Calgar & Associates an aggregate of \$950,000 in cash and issued 236,298 shares of common stock in lieu of cash payments of \$600,000. We are also obligated to pay Dr. Weg, Mr. Brotspies, and Calgar & Associates a royalty on the sales, net of various customary cash discounts, attributable to intranasal ketamine.

#### **Sales and Marketing**

Our commercialization efforts will focus on a dual-path marketing and distribution strategy as a result of our areas of therapeutic focus. A narrow channel of distribution will target hospitals, chronic care facilities, palliative care providers, long-term care centers, pain specialists, high-prescribing oncologists, oncology clinics, burn clinics, and customers such as the U.S. Department of Defense. This focused approach allows for the creation of a small internal sales and marketing organization. In addition to building our own sales and marketing organization, we are also evaluating the utilization of a broader channel of distribution such as large, established pharmaceutical companies and contract sales organizations to assist in the broadest commercialization of our product candidates. In order to cover all of the key prescribing physicians at an adequate level of reach and frequency, we would need to significantly expand our proposed sales force or partner with a company with a substantial sales organization. Outside of the U.S. we intend to sublicense distribution and marketing rights to one or more pharmaceutical companies with established sales forces in the targeted territories.

## Competition

Our success will depend, in part, upon our ability to achieve market share at the expense of existing, established products and future products in the relevant target markets. Existing and future products, therapies, technological innovations, and delivery systems will compete directly with our products. Competing products and technologies may provide greater therapeutic benefit for a specific indication or may offer comparable performance at a lower cost. Alternative technologies are being developed to improve the delivery of drugs within the prescription pain management industry, several of which may be in the clinical trials stage or are awaiting approval from the FDA.

We compete with fully integrated pharmaceutical companies, smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies, and other public and private research institutions. Many companies, for example, currently sell either generic or proprietary prescription pain formulations. Companies that currently sell both generic and proprietary opioid formulations include among others Abbott Laboratories, Alza Pharmaceuticals, AstraZeneca, Cephalon, Endo Pharmaceuticals, Elkins-Sinn, Janssen Pharmaceutica, McNeil Consumer Healthcare, Purdue Pharma, Roxane Laboratories and Watson Laboratories. Alternative technologies are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. These alternatives include Elan's Prialt, Pfizer's Lyrica as well as combination products from Endo Pharmaceuticals. In addition, companies pursuing different but related fields represent substantial competition. Such competitors may also have access to more resources, financial and otherwise, which may allow these institutions to develop and market competing products more rapidly and more effectively than we have. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in developing drugs, undertaking preclinical testing and human clinical trials, obtaining FDA and other regulatory approvals of drugs, formulating and manufacturing drugs and launching, marketing and selling drugs.

## Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other relevant proprietary technologies, preserve our trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy has been to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents.

We currently have exclusive licenses to eight issued U.S. patents and their foreign equivalent patents and patent applications, as well as five of our own pending U.S. patent applications, each of which is also the subject of foreign equivalent applications.

The issued U.S. patents that have been exclusively licensed to us, and the product candidates (or uses thereof) that we believe are likely to be covered by the claims of those patents, are:

Patent Numbers	Product Candidate	Expiration Date
5,989,582	Intranasal ketamine	Feb. 25, 2014
6,248,789	Intranasal ketamine	Feb. 25, 2014
5,543,434	Intranasal ketamine	Feb. 25, 2014
5,679,714	Intranasal ketamine	Oct. 21, 2014
5,744,166	Rylomine (intranasal morphine)	Aug. 21, 2011
5,629,011	Rylomine (intranasal morphine)	May 13, 2014
5,554,388	Rylomine (intranasal morphine)	Sept. 10, 2013
5,679,660	Dyloject (injectable diclofenac)	Dec. 2, 2014

To the extent our pending patent applications are issued, if at all, they will only provide us with protection for the claims set forth in those patents when issued. We believe that, if issued, the claims in one of our pending patent applications is likely to cover our Rylomine (intranasal morphine) product candidate, the claims in two of our pending patent applications are likely to cover our intranasal ketamine product candidate, and that the claims in two of our pending patent applications could cover a new formulation of our Dyloject (injectable diclofenac) product candidate. We also have an exclusive license to a U.S. pending patent application and its foreign equivalents that, if issued, we believe is likely to cover our Dyloject (injectable diclofenac) product candidate.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we will rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

The names Dyloject and Rylomine are registered trademarks in the European Union, and in the U.S. we have filed "intent-to-use" trademark applications for these names, both of which have been allowed. We also have pending "use-based" trademark applications in the U.S. for the name "Javelin", our logo and our name used in combination with our logo.

## **Manufacturing**

We do not own any manufacturing facilities. We contract with qualified third parties that must comply with current good manufacturing practices and procedures reviewed by the FDA for the manufacture of bulk active pharmaceutical ingredients and finished product. Historically, we have worked with several manufacturing vendors including, most recently, DPT Lakewood, Inc. for the clinical supply of PMI-150 and Rylomine™. In addition, in February 2007 we entered into a Commercial Supply Agreement (the "Supply Agreement") with Precision Pharma Services, Inc., pursuant to which Precision Pharma agreed to manufacture our requirements for the supply of Dyloject™, in accordance with U.S. and E.U. good manufacturing practices. We committed to purchase at least \$7,650,000 worth of product during the two year period beginning on April 1, 2007. The initial term of the Supply Agreement is two years, and it is renewable in one-year increments. We were advised that the FDA has inspected and approved the facilities of both DPT Lakewood, Inc. and Precision Pharma, and that both facilities were determined to be in compliance with good manufacturing practices.

We believe that the raw materials needed for production of our product candidates are readily available from alternative supplies. However, as part of the regulatory approval process we must specify the manufacturing process and the particular raw materials to be used. Changes in the materials or the manufacturer could be subject to prior regulatory approval.

## **Government Regulation**

The FDA and comparable regulatory agencies in foreign countries as well as pharmacy regulators in state and local jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products.

The process required by the FDA under the drug provisions of the United States Food, Drug, and Cosmetic Act before our initial products may be marketed in the U.S. generally involves the following:

- preclinical laboratory and animal tests;
- submission of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a NDA; and
- FDA review and approval of a NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

We then submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations. These regulations include the requirement that all subjects provide informed consent. Further, an independent Institutional Review Board ("IRB") at each medical center proposing to conduct the clinical trials must review and approve any clinical study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur.

Human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase II: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase III: When Phase II evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage and clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the IRB, or us as IND sponsor, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Under the Pediatric Research Equity Act of 2003, a sponsor is also required to include an assessment, generally based on clinical study data, on the safety and efficacy of its drugs for all relevant pediatric populations before it submits an NDA. The statute provides for waivers or deferrals in certain situations, and we intend to submit applications for such waivers or deferrals, but we can make no assurances that such situations will apply to our products or that the waivers or deferrals will be granted.

We also must finalize a process for manufacturing the product in accordance with current good manufacturing practice ("GMP") requirements. The manufacturing process must be capable of consistently producing quality batches of the product, and we must develop methods for testing the quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

The results of product development, pre-clinical studies, and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. The FDA conducts an initial review of each NDA submitted to assess whether it is acceptable for filing. The FDA may refuse to file the NDA and may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the FDA accepts the NDA for filing, the agency begins an in-depth review of the NDA. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the NDA. The review process may be significantly extended by the FDA requests for additional information or clarification regarding information already provided. Also, as part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. Manufacturing establishments often also are subject to inspections prior to NDA approval to assure compliance with GMPs.

The FDA's response to the NDA will be in the form of an approval letter, an approvable letter or a non-approvable letter. Any response from the FDA that is not approval of the NDA may require us to submit additional information, which may include additional clinical data. Even if the FDA approves the NDA, the agency may decide later to withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market. The FDA may require post-approval studies, also known as Phase IV studies, to develop additional information regarding the product. In addition, the FDA requires post-approval adverse event reporting, and the agency has the power to require changes in labeling or to prevent further marketing of a product. The agency may also decide later to withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market.

Under the Prescription Drug User Fee Act ("PDUFA"), submission of an NDA with clinical data requires payment of a fee. For fiscal year 2007, that fee is \$896,200. In return, the FDA assigns a goal of ten months for standard NDA reviews from acceptance of the application to the time the agency issues its response. It is not certain that the FDA will meet its performance goal of ten months for its review. The PDUFA will expire on September 30, 2007. Congress is considering proposals to reauthorize PDUFA, and the FDA has announced that it may request that Congress substantially increase annual PDUFA fees. On January 30, 2007, the FDA also announced a renewed commitment to drug safety that may in part be implemented through changes to the PDUFA. We do not know how our company or the cost of developing and commercializing our product candidates will be affected by changes to PDUFA that may become effective if and when the PDUFA is reauthorized, or by the FDA's renewed commitment to drug safety.

Satisfaction of the above FDA requirements or requirements of state, local and foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our products under development

on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, regulatory approvals would have a material adverse effect on our business.

Any products we manufacture or distribute pursuant to the FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with the FDA promotion and advertising requirements. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. However, in certain circumstances, and subject to very stringent requirements, the FDA will permit the dissemination of peer-reviewed scientific reprints related to unapproved uses. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with current good manufacturing practices, which impose procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with these regulations could result, among other things, in warning letters, suspension of regulatory approval, refusal to approve pending applications or supplements to approved applications filed by us, recalls, suspension or closure of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with those regulations and other FDA regulatory requirements.

We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

In addition, whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of clinical trials and subsequent sales and marketing efforts in those countries. The approval procedure varies in complexity from country to country, and the time required may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future.

### **Other Regulatory Requirements**

The U.S. Federal Trade Commission and the Office of the Inspector General of the U.S. Department of Health and Human Services ("HHS") also regulate certain pharmaceutical marketing practices. Thus, reimbursement practices of the HHS covering medicine and medical services are important to the success of our products.

The federal Controlled Substances Act ("CSA") imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, import and export controls, labeling and packaging requirements, security controls, and a restriction on prescription refills on certain pharmaceutical products. Most states impose similar controls over controlled substances under state law as regulated by the Board of Pharmacy or other state regulatory authorities. The CSA is administered by the DEA, a division of the Department of Justice. To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure of companies to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action, including civil and criminal penalties, refusal to renew necessary registrations, or initiating proceedings to revoke those registrations. If a manufacturer or distributor has its registration revoked, it can no longer lawfully possess or distribute controlled substances, meaning effectively that the operations of such an organization must cease with respect to controlled substances. In certain circumstances, violations also can lead to criminal proceedings.

A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be "scheduled" as a Schedule I, II, III, IV or V substance, with Schedule II substances considered to present the highest risk of substance abuse for any product with a medical use, and Schedule V substances the lowest. Morphine and ketamine are classified as Schedule II and III substances, respectively. As a Schedule III substance, each substance prescription for our ketamine product would be limited to five refills. Morphine, however, as a Schedule II substance would be subject to higher regulation, including no refills for prescriptions, special transactions reporting to the DEA, special DEA-supplied order forms for all transactions, and written prescriptions instead of prescriptions phoned or faxed to a pharmacy. The DEA also limits the quantity of the Schedule II controlled substance inventories used by pharmaceutical manufacturers in the production of controlled substances. As part of the commercialization of our morphine product, we, our subcontractors or our vendors will be required to file for and obtain quotas from the DEA for the procurement and manufacture of controlled substance active ingredients and finished drug products.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations now or in the future. We cannot assure you that any portion of the regulatory framework under which we currently operate will not change and that such change will not have a material adverse effect on our current and anticipated operations.

All three of our product candidates are in late stage development as shown below:

Product candidate	Territory	Indication	Development stage
Dyloject™ (injectable diclofenac)	U.S. Europe	Post-operative pain Post-operative pain, anti-inflammatory	Phase III MAA Review
PMI-150 (intranasal ketamine)	U.S.	Acute moderate-to-severe pain	Completing registration studies
Rylomine™ (intranasal morphine)	U.S.	Acute moderate-to-severe pain	Phase III

The End-of-Phase II FDA meeting is usually required in order to progress into Phase III trials and ultimately product registration. The FDA typically schedules the End-of-Phase II meeting within six weeks of the meeting request, if accepted. If not accepted, the FDA informs the company of insufficiencies to be rectified in order to reschedule. The design, timing and cost of the Phase III development program will be largely determined by the clinical safety and efficacy data and feedback from the FDA at the End-of-Phase II meeting. We held the Rylomine™ End-of-Phase II meeting with the FDA in the first quarter of 2006 and commenced patient enrollment in the Phase III program in May 2006. In the second quarter of 2006, our End-of-Phase II meeting for Dyloject™ took place. Patient enrollment in the Phase III program for this product candidate commenced in the second quarter of 2006. We met with the FDA in January 2007 to finalize the development plan for PMI-150. At this meeting, the FDA indicated that no additional clinical efficacy trials would be needed prior to filing an initial NDA. Therefore, we intend to undertake four remaining pharmacokinetic studies and then to file an NDA for PMI-150 as an emergency analgesic for military and civilian use in 2008. With respect to other potential applications for PMI-150, we are preparing to commence Phase III clinical trials.

### European Product Approval

Prior regulatory approval for human healthy volunteer studies (Phase I studies) is required in member states of the E.U. Following successful completion of Phase I studies, data is submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase II studies. The regulatory authorities in the E.U. typically have between one and three months to raise any objections to the proposed study, and they often have the right to extend this review period at their discretion. In addition, one or more independent ethics committees, which typically operate similarly to an Institutional Review Board in the U.S., will review the ethics of conducting the proposed research.

In order to gain marketing approval in the E.U., we must submit a dossier to the relevant authority for review, which is known in the E.U. as a MAA (marketing authorization application). The format is usually specific and laid out by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as the non-clinical and clinical data.

In the E.U. there is, for many products, a choice of two different authorization routes: centralized and decentralized. Under the centralized route, which we are pursuing for our intranasal morphine product, one marketing authorization is granted for the entire E.U., while under the decentralized route, which we are pursuing for IV diclofenac, a series of national marketing authorizations are granted. In the centralized system the application will be reviewed by members of the Committee for Proprietary Medicinal Products ("CPMP"), on behalf of EMEA. The EMEA will, based upon the review of the CPMP, provide an opinion to the European Commission on the safety, quality and efficacy of the product. The decision to grant or refuse an authorization is made by the European Commission. In circumstances where use of the centralized route is not mandatory, we can choose to use the decentralized route, in which case the application will be reviewed by one member state's regulatory agency. If the regulatory agency grants the authorization, other member states' regulatory authorities are asked to "mutually recognize" the authorization granted by the first member state's regulatory agency.

Approval can take several months to several years, or can be denied. The approval process can be affected by a number of factors. Additional studies or clinical trials may be requested during the review and may delay marketing approval and involve unbudgeted costs. The regulatory authorities may conduct an inspection of relevant facilities and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing

surveillance to monitor for adverse effects, or other additional studies as deemed appropriate. After approval for the initial indication, further clinical studies are usually necessary to gain approval for any additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

Failure to comply with applicable regulatory requirements after obtaining regulatory approval can, among other things, result in the suspension of regulatory approval, as well as possible civil and criminal sanctions. Renewals in Europe may require additional data, which may result in a license being withdrawn. In the E.U., regulators have the authority to revoke, suspend or withdraw approvals of previously approved products, to prevent companies and individuals from participating in the drug approval process, to request recalls, to seize violative products and to obtain injunctions to close manufacturing plants not operating in conformity with regulatory requirements and to stop shipments of violative products.

Our lead product in Europe is Dyloject™. In July 2005, we announced that we had met our primary endpoint in the pivotal European Phase II/III study for Dyloject. In September 2005, at the European Society of Regional Anesthesia and Pain Therapy (ESRA) annual meeting, we presented the final results of this randomized, double-blind, placebo- and comparator-controlled Phase II/III pivotal clinical trial comparing the safety, efficacy and therapeutic equivalency of Dyloject™ to Voltarol®. An MAA (marketing authorization application) submission for approval to sell this product in Europe was filed in September 2005 and the MHRA granted allowance in October 2005. The review and approval process typically takes between 12 to 18 months for marketing authorization, rejection, or approval subject to completion of additional requirements imposed on the company by the regulatory agency at the time of review completion. Should we receive approval for Dyloject™, we will also continue to take the necessary steps to facilitate a product launch, including distribution, marketing and sales activities beginning in the U.K. with the intent to further distribute, market and sell the product throughout certain European countries.

In September 2004, the EMEA's Committee for Medicinal Products for Human Uses, appointed France as the Rapporteur country that will be responsible along with Germany for reviewing the Rylomine MAA filing. In October 2005, we announced that we had met our primary endpoint of a linear dose response for pain relief over four hours in a Phase IIb study of Rylomine™. In February 2006, at the American Academy of Pain Medicine annual meeting, we presented comprehensive results of this randomized, double-blind, placebo- and comparator-controlled clinical trial comparing the safety and efficacy of Rylomine™ to IV morphine. This study demonstrated that patients with moderate-to-severe pain after orthopedic surgery who received Rylomine™ or intravenous morphine experienced statistically significant pain relief over four hours compared to patients who received a placebo. In April 2006, we announced that we held our End-of-Phase II meeting with the FDA and in May 2006, we initiated the U.S. Rylomine™ Phase III clinical program. We are also focused on seeking regulatory and scientific advice from French regulatory experts and the European Agency for Evaluation of Medicinal Products. The results of the clinical trials along with feedback from the regulatory agencies will determine the timing, extent and cost of the European Rylomine™ development program and product filings.

### **Pricing Controls**

Before a pharmaceutical product may be marketed and sold in certain foreign countries the proposed pricing for the product must be approved. The requirements governing product pricing vary widely from country to country and can be implemented disparately at the national level.

The E.U. generally provides options for its member states to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, the regulation of prices of pharmaceuticals in the United Kingdom is generally designed to provide controls on the overall profits that pharmaceutical companies may derive from their sales to the U.K. National Health Service. The U.K. system is generally based on profitability targets or limits for individual companies which are normally assessed as a return on capital employed by the company in servicing the National Health Service market, comparing capital employed and profits.

In comparison, Italy generally establishes prices for pharmaceuticals based on a price monitoring system. The reference price is the European average price calculated on the basis of the prices in four reference markets: France, Spain, Germany and the U.K. Italy typically establishes the price of medicines belonging to the same therapeutic class on the lowest price for a medicine belonging to that category. Spain generally establishes the selling price for new pharmaceuticals based on the prime cost, plus a profit margin within a range established each year by the Spanish Commission for Economic Affairs. Promotional advertising costs are limited.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceuticals will allow favorable reimbursement and pricing arrangements for our products.

### **Third-Party Reimbursements**

In the U.S., E.U. and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability and adequacy of reimbursement to the consumer or the health care provider from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit.

In the U.S., the willingness of consumers to choose treatment with a self-administered outpatient prescription drug over a different drug, or over another form of treatment, is often dependent in part upon the success of the manufacturer in obtaining placement of the product on their health plan's formulary or drug list, because favorable formulary placement means lower out of pocket costs. Obtaining favorable formulary placement typically requires that the product be less expensive than what the health plan determines to be therapeutically equivalent products, and often requires manufacturers to offer discounts or rebates. Federal law also requires manufacturers to pay rebates to state Medicaid programs in order to have their products reimbursed by Medicaid. Beginning in the summer of 2004, Medicare sponsored a prescription drug discount card program that is intended to reduce costs for prescription drugs, and beginning in 2006, a new Medicare Part D offered eligible beneficiaries limited coverage for outpatient prescription drugs. Both of these programs rely on formularies. These modifications to Medicare payment formulas include those for prescription drugs administered in a provider setting, such as a hospital or physician's office, and are generally designed to lower reimbursement for those drugs.

The E.U. generally provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states in the E.U. can opt to have a "positive" or a "negative" list. A positive list is a listing of all medicinal products covered under the national health insurance system, whereas a negative list designates which medicinal products are excluded from coverage. The E.U., the U.K. and Spain use a negative list approach, while France uses a positive list approach. In Canada, each province decides on reimbursement measures. In some countries, in addition to positive and negative lists, products may be subject to a clinical and cost effectiveness review by a health technology assessment body. A negative determination by such a body in relation to one of our products could affect the prescribing of the product. For example, in the U.K., the National Institute for Clinical Excellence ("NICE") provides guidance to the National Health Service on whether a particular drug is clinically effective and cost effective. Although presented as "guidance," doctors are expected to take the guidance into account when choosing a drug to prescribe. In addition, health authorities may not make funding available for drugs not given a positive recommendation by the NICE. There is a risk that a negative determination by the NICE will mean fewer prescriptions. Although the NICE will consider drugs with orphan status, there is a degree of tension on the application by the NICE of the standard cost assessment for orphan drugs, which are often priced more highly to compensate for the limited market. It is unclear whether the NICE will adopt a more relaxed approach toward the assessment of orphan drugs.

We cannot assure you that any of our products will be considered cost effective and that reimbursement to the consumer or the health care provider will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

### **Fraud and Abuse Laws**

A federal law commonly known as the federal healthcare program anti-kickback law, and several similar state laws, prohibit any remuneration that is intended to induce physicians or others either to refer patients, or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal health care program, the state laws often apply regardless of whether federal funds may be involved. Other federal and state laws prohibit anyone from presenting or causing to be presented claims for payment to health care payers that are false, fraudulent or are for items or services not provided as claimed. Several recent and current enforcement actions by federal and state prosecutors have targeted some sales and marketing activities of prescription drug manufacturers under these statutes. As we begin to market our products to health care providers, such as physicians and hospitals, the relationships we form, including compensation of physicians for speaking or consulting services, financial support of continuing medical education or research programs, and assisting customers with obtaining third-party reimbursement for its products, could be challenged under these broad laws. A successful challenge could lead to civil or criminal penalties, including the exclusion of our products from reimbursement under Medicare, Medicaid, U.S. military health care or other federally-funded health care programs. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. It is our intention to consult with experienced counsel concerning the potential application of these and other laws to our business and to attempt to structure our sales, marketing and other activities to comply with all such laws. However, given the broad reach of these laws and the increasing attention being given to them by law enforcement authorities, we cannot assure you that some of our activities will not be subject to challenge in the future.

## Employees

As of December 31, 2006, we had 28 full-time employees and two temporary employees. We intend to employ additional employees or retain persons as consultants as needed, depending on the availability of such persons.

## Internet Web Site

Our website is located at: <http://www.javelinpharmaceuticals.com>.

## Available Information

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

## ITEM 1A. RISK FACTORS

Following are some specific factors that should be considered for a better understanding of our operations and financial condition. These factors and the other matters discussed herein are important factors that could cause actual results or outcomes for us to differ materially from those discussed in the forward-looking statements included elsewhere in this report. New factors emerge from time to time, and it is not possible for us to predict all of the factors, nor can we assess the effect of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

### Risks Related to Our Business

**We currently have no product revenues and cannot be certain when product revenues will commence, if ever.**

To date, we have devoted significant financial resources to research and development of our products. Until, and if, we receive approval from the FDA and from regulatory authorities in foreign jurisdictions for our product candidates, we cannot sell our products and we will not have product revenues. As a result, we have generated significant operating losses. As of December 31, 2006, we had an accumulated deficit of \$79.4 million, excluding approximately \$3.6 million deemed dividend; although \$18.6 million of this amount was related to a non-cash charge we incurred in connection with a research and development write-off related to our formation. We used substantial amounts of cash to date and expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and development activities. We expect to fund our operations and capital expenditures primarily from cash on hand and additional financing initiatives.

**If we cannot obtain additional financing, our product development and commercialization efforts may be reduced or discontinued.**

Although we believe that our existing cash and cash equivalents will be sufficient to support the current operating plan through at least June 30, 2007, we will need additional financing to support our operating plan thereafter. Our funding requirements may change as a result of many factors, including delays in development activities, underestimates of budget items, unanticipated cash requirements, increased regulatory requirements with attendant time delays, limitation of development of new potential products, future product opportunities with collaborators, future licensing opportunities and future business combinations. Consequently, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all.

We plan to raise additional financing through public or private equity offerings, debt financings and/or additional corporate collaboration and licensing arrangements. The issuance or perceived issuance of additional equity securities in connection with any financing will cause dilution to our shareholders and could have a material negative effect on the price of our common stock. If we raise additional capital by issuing debt securities, we would incur substantial costs relating to interest payments, may be required to pledge assets as security for the debt and may be constrained by restrictive financial and/or operational covenants. If we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue

product development, curtail operations, reduce or forego sales and marketing efforts and lose attractive business opportunities. These actions would likely reduce the price of our common stock.

**We have incurred significant losses and may never achieve or sustain profitability.**

We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future, and we may not achieve or maintain profitability. For the years ended December 31, 2004, 2005 and 2006, we had net losses of \$7.0 million, \$10.6 million and \$17.8 million, respectively. Our net loss for the year ended December 31, 2006 was materially increased as compared to prior fiscal years due to our adoption of the amendment issued by the Financial Accounting Standards Board to Statement of Financial Accounting Standards No. 123, *Accounting For Stock-Based Compensation* ("SFAS No. 123R"). As discussed in Note 2, "Summary of Significant Accounting Policies," in the notes to the condensed consolidated financial statements included in our Form 10-K for the fiscal year ended December 31, 2006, we adopted SFAS No. 123R effective January 1, 2006. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25, and instead requires us to recognize compensation expense using a fair-value based method for costs related to share-based payments including stock options. Our adoption of SFAS No. 123R is expected to materially impact our financial position and results of operations for future periods.

Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures for the next several years and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake pre-clinical development and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- lease additional office facilities;
- hire additional personnel to advance commercialization; and
- expand research and development activities.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

**We have a limited operating history upon which to base an investment decision.**

We are a development-stage company and have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products;
- entering into arrangements with manufacturers; and
- conducting sales and marketing activities either directly or through distributors.

Our operations have been limited to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking pre-clinical trials and clinical trials of our principal product candidates. These operations provide a limited basis to assess our ability to commercialize our product candidates and the advisability of investing in our common stock.

**We will incur increased costs and management time in seeking to implement the requirements of the Sarbanes-Oxley Act of 2002 and other corporate regulations.**

Since late 2004, our SEC reporting status has evolved from "small business" issuer to "non-accelerated" full reporting issuer to "accelerated" filer becoming subject to Section 404 of The Sarbanes-Oxley Act of 2002. By reason of this reporting status, as well as new disclosure rules o

the Securities and Exchange Commission (the "SEC") and the American Stock Exchange, our legal and financial compliance costs have substantially increased and a significant portion of management's time has been allocated in order to comply with these rules, especially with respect to compiling the initial comprehensive documentation of our internal controls, and then evaluating and testing the operating effectiveness of our internal controls systems in seeking compliance with Section 404. If we do not adequately comply with the Section 404 requirements, we may not be able to accurately report our financial results and might become subject to investigation by regulatory authorities. Any disclosure of inability to meet such compliance could be detrimental to investors' confidence in us, and thereby adversely affect the price of our common stock.

**If we fail to obtain or maintain the necessary U.S. or foreign regulatory approvals for our product candidates, we will be unable to commercialize them.**

Government regulations in the U.S. and other countries have a significant impact on our business and affect the research and development, manufacture and marketing of our products. We will require FDA approval to commercialize our product candidates in the U.S. and approvals from similar regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA an NDA, demonstrating that our product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal testing, which are referred to as pre-clinical studies, as well as human studies, which are referred to as clinical trials. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may either refuse to accept our application, or may decide after review of our application that the data is insufficient to allow approval of the relevant product. If the FDA does not accept or approve our application, it may require us to conduct additional pre-clinical testing, manufacturing studies or clinical studies and submit that data before it will reconsider our application. The FDA may also require us to perform post-approval studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures; and
- diminish competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be certain that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our principal product candidates will severely undermine our business by reducing the number of potential salable products and, therefore, corresponding product revenues. Also, the FDA might approve one or more of our product candidates but may also approve competitors' products possessing characteristics that offer their own treatment advantages.

Before we submit our NDAs, we plan to request waivers or deferrals from the requirement under the Pediatric Research Equity Act of 2003 to include an assessment, generally based on clinical study data, of the safety and efficacy of our drugs for all relevant pediatric populations. We can make no assurances that the FDA will grant our waiver or deferral requests. If we are required to conduct clinical research studies in pediatric patients, this could delay the development and possible approval of our products and increase the overall costs of product approvals.

In addition, even after these product candidates are marketed, our products and the manufacturers are subject to continual vigilance and review by applicable regulatory authorities, including FDA adverse event reporting requirements and FDA requirements governing product distribution, advertising and promotion. At any stage of development or commercialization, the discovery of previously unknown problems with our product candidates, our own manufacturing or the manufacture by third-party manufacturers may result in restrictions on our products or the manufacture, including withdrawal of our product from the market.

In foreign jurisdictions, we must receive approval from the appropriate regulatory, pricing and reimbursement authorities before we can commercialize and market our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. Pursuing foreign regulatory approvals will be time-consuming and expensive. The regulations vary among countries, and foreign regulatory authorities may require different or additional clinical trials than we conducted to obtain FDA approval for our product candidates. We cannot give any assurance that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

Because we have limited foreign regulatory, clinical and commercial resources, we may plan to commercialize some products internationally through collaborative relationships with foreign partners. Future partners are critical to our international success. We may not be able to enter into collaboration agreements with appropriate partners for important foreign markets on acceptable terms, or at all. Future collaborations with foreign partners may not be effective or profitable for us.

**Our product candidates contain controlled substances, the supply of which may be limited by U.S. government policy and the availability of which may generate public controversy, thereby reducing or restricting any future marketing arrangements or sales.**

The active ingredients in some of the current product candidates, including morphine and ketamine, are regulated by the U.S. Drug Enforcement Administration ("DEA"), as Schedule II or III substances under the Controlled Substances Act of 1970. Most states place similar controls over these products under the Board of Pharmacy or similar agency. Consequently, their manufacture, shipment (including import and export), storage, sale and use are subject to the highest degree of regulation and accountability. For example, all regular Schedule II drugs must be prescribed by a physician, or under a physician's direction, and may not be refilled within 30 days. Furthermore, the amount of Schedule II substances we can obtain for clinical trials, manufacturing and commercial distribution is limited by the DEA under a quota system, and our allotment may not be sufficient to complete clinical trials or meet commercial demand, if any. Any delay or refusal by the DEA in establishing our procurement quota of such substances could have a material adverse effect on our business, financial position and results of operations.

Products containing controlled substances may generate public controversy. The World Health Organization advocates balance in national analgesic policies, so as to meet medical needs for opioids and other controlled substances while reducing opportunities for drug abuse, misuse and diversion. Opponents of these products, however, may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products. Political pressures and adverse publicity could lead to delays in the introduction and marketing of our product candidates, increased expenses for marketing, and/or restricted availability of our product candidates. Our contract manufacturers that make and handle controlled substances also are subject to inspections by DEA and state authorities to evaluate ongoing compliance with security and other requirements under relevant federal and state controlled substance laws and regulations. We do not have control over the contract manufacturers' compliance with these regulations and standards. Failure to comply with applicable laws and regulatory requirements may result in action such as civil penalties, refusal to renew necessary registrations, or initiating proceedings to revoke those registrations and, in certain circumstances, criminal proceedings. If one of these manufacturers has its registration revoked, denied or suspended, it can no longer lawfully possess or distribute controlled substances, thereby possibly resulting in a negative impact on our business.

**Our product candidates are in the late stages of clinical trials in the United States, and there is no assurance that final approval will be obtained.**

Our product candidates may never be successfully marketed or manufactured. Our three principal product candidates, Dyloject™, PMI-150 and Rylomine™, are in the late stages of clinical testing in the United States on a limited number of patients. For some medical uses for which we hope to market our products, to date there have been few or no studies to determine the efficacies of the specific product candidates. It also is possible that the FDA will disagree with our current clinical and pre-clinical research plans and require us to conduct more extensive studies than we currently anticipate before that agency will consider our products for marketing approval. Some of our future studies involve drug exposures for durations that are significantly longer than we have tested thus far. The longer-term studies could reveal safety or other issues that could have an adverse impact on the ability to gain marketing approval. We need to commit substantial time and resources in order to conduct further clinical trials before we can submit an NDA with respect to any of these product candidates. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval of any of our product candidates.

**Clinical trials are expensive, time-consuming and difficult to design and implement, which could affect allocations of funds and time from other programs.**

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, the medical, regulatory and commercial environment for pharmaceutical products changes quickly and often in ways that we may not be able to accurately predict. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates will take several more years to complete. Furthermore, as failure can occur at any stage of the trials, we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes to applicable regulatory requirements;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness in the clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols;

- inability to maintain a supply of the investigational drug in sufficient quantities to support the trials; and
- suspension or termination of clinical trials for various reasons, including noncompliance with regulatory requirements or changes in the clinical care protocols and standards of care within the institutions in which our trials take place.

In addition, we or the FDA may suspend the clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug Application submissions or the conduct of these trials.

A number of companies in the biotechnology and drug development industry have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products.

**The results of the clinical trials are uncertain and may not support our product candidate claims.**

Even if the clinical trials are completed as planned, we cannot be certain that the results will support our product candidate claims or that the FDA or government authorities will agree with our conclusions regarding such results. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, the clinical trials will delay the filing of NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, the clinical trials involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

**Delays in patient enrollment for clinical trials could increase costs and delay regulatory approvals.**

The rate of completion of clinical trials will depend on the rate of patient enrollment. There may be substantial competition to enroll patients in clinical trials for other products in development. This competition has delayed the clinical trials of other biotechnology and drug development companies in the past. In addition, ongoing improvements in drug therapy, particularly for pain management drugs, may make it more difficult for us to enroll patients in our clinical trials as the eligible patient population may choose to enroll in clinical trials sponsored by other companies or choose other recently-approved therapies. Delays in patient enrollment can result in increased development costs and delays in regulatory approvals.

**Physicians and patients may not accept and use our drugs, which would cause a change in the business strategy with attendant delays and needs for capital for any new business, and possibly the cessation of business.**

Even if the FDA and/or applicable foreign regulatory agencies approve our drugs, physicians and patients may not accept and use them. Acceptance and use of these drugs will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of these drugs and the use of controlled substances;
- cost-effectiveness of these drugs relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of the current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

**Our ability to generate product revenues will be diminished if the drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement, thereby reducing future levels of revenues and the ability to achieve profitability.**

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payors.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, routinely challenge the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate to cover such drugs. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products, the post-approval market acceptance of our products could be diminished.

**The drug-development programs depend in large part upon third-party researchers who are outside our control.**

We depend upon independent investigators and collaborators, such as universities, medical institutions and clinical research organizations, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to these drug-development programs, or if their performance is substandard, the approval of our FDA applications, and our introduction of new drugs, will be delayed. These collaborators may also have relationships with other commercial entities, some of which may compete with us. If these collaborators assist our competitors at our expense, our competitive position would be harmed.

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

We have relied exclusively and are dependent on certain third party single source suppliers to supply raw materials and finished goods for our product candidates. The loss of one or more of these suppliers, if not replaced, could have a material adverse effect on our business. The FDA and regulatory agencies in other countries also periodically inspect manufacturing facilities, including third parties who manufacture products or active ingredients for us. The FDA and/or applicable foreign regulatory agencies may not believe that the chosen manufacturers have sufficient experience making the dosage forms that we have contracted with them to produce, and may subject those manufacturers to increased scrutiny. Pharmaceutical manufacturing facilities must comply with applicable good manufacturing practice standards, and manufacturers usually must invest substantial funds, time and effort to ensure full compliance with these standards. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure to comply with applicable regulatory requirements can result in sanctions, fines, delays or suspensions of approvals, seizures or recalls of products, operating restrictions, manufacturing interruptions, costly corrective actions, injunctions, adverse publicity against us and our products and possible criminal prosecutions.

If we are unable to obtain sufficient supplies of raw materials or if there is a significant increase in the price of raw materials, our business would be seriously harmed. If any of our product candidates receives the approval of the FDA and/or applicable foreign regulatory agencies, we expect to rely on one or more third-party contractors to supply our drugs. If any current or future third-party suppliers cease to supply the drugs in the quantity and quality we need to manufacture the drug candidates or if the current or future third-party suppliers are unable to comply with good manufacturing practice and other government regulations, the qualification of additional or replacement suppliers could be a lengthy process, and there may not be adequate alternatives to meet our needs, which would negatively affect our business. We may not be able to obtain the necessary drugs used in our products in the future on a timely basis, if at all.

**If we are unable to hire additional qualified personnel, our ability to grow the business may be harmed. We must hire and retain skilled employees in a tight labor market and will be subject to high labor costs and related increased employment expenses.**

We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, finance and accounting and sales and marketing. We will compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the Boston metropolitan area, is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Skilled employees in the industry are in great demand. We are competing for employees against companies located in the Boston metropolitan area that are more established than we are and have the ability to pay more cash compensation than we do. We will require scientific personnel in many fields, some of which are addressed by relatively few companies. As a result, depending upon the success and the timing of clinical tests, we may experience difficulty in hiring and retaining highly skilled employees, particularly scientists. If we are unable to hire and retain skilled scientists, our business, financial condition, operating results and future prospects could be materially adversely affected.

**We have limited experience in marketing and selling our products, and we may need to rely on a third party collaborator to do so.**

We currently have no designated sales and marketing staff, nor any internal sales or distribution capabilities. In order to commercialize our products, if any are approved, we intend to develop internal sales, marketing and distribution capabilities to target particular markets for our

products, as well as make arrangements with third parties to perform these services for us with respect to other markets for our products. We may not be able to establish these capabilities internally or hire sales personnel with appropriate expertise to market and sell our products, if approved. In addition, even if we are able to identify one or more acceptable collaborators to perform these services for us, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

If we enter into any collaborative arrangements for the marketing or sale of our products, our product revenues are likely to be lower than if we marketed and sold our products ourselves. In addition, any revenues we receive would depend upon the efforts of our collaborators, which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, business combinations or other factors outside of our control. Depending upon the terms of the collaboration, the remedies we may have against an underperforming collaborator may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, if at all.

**If our products are not accepted by the market, or if we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues, and our business will suffer.**

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA or foreign approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues, and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have prescription analgesics already approved or in development. In addition, many of these competitors, either alone or together, with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

The United States Food, Drug, and Cosmetic Act and FDA regulations and policies provide incentives to manufacturers to challenge patent validity or create modified, noninfringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same incentives also encourage manufacturers to submit new drug applications, known as 505(b)(2) applications, that rely on literature and clinical data not generated by or for the drug sponsor. In light of these incentives and especially if our products are commercially successful, other manufacturers may submit and gain approval for either an abbreviated new drug application or a 505(b)(2) application that will compete directly with our products.

**Developments by competitors may render our products or technologies obsolete or noncompetitive.**

Companies that currently sell both generic and proprietary opioid formulations include among others Abbott Laboratories, Alza Pharmaceuticals, AstraZeneca, Cephalon, Endo Pharmaceuticals, Elkins-Sinn, Janssen Pharmaceutica, McNeil Consumer Healthcare, Purdue Pharma, Roxane Laboratories and Watson Laboratories. Alternative technologies are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or have recently been approved by the FDA. These alternatives include Elan's Prialt, Pfizer's Lyrica, and combination products from Endo Pharmaceuticals. In addition, companies pursuing distinct but related fields such as neuromodulation devices represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than us. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

**If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, we may be unable to protect or exploit our intellectual property rights.**

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to obtain trademarks for our name, logo and products, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We are aware of a third party which could allege that certain uses of our product candidates infringe upon certain of such third party's proprietary rights. Although we do not intend to market our product candidates for such uses and we are not aware of any such uses currently in practice, we may not be able to avoid claims made by such third party as a result of our product candidates being used by consumers for purposes other than as marketed by us.

We have exclusive licenses to certain patent rights, including rights under U.S. patents and U.S. patent applications as well as rights under equivalent foreign patents and patent applications, and we also own pending U.S. patent applications and foreign equivalents. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors including whether third parties will find ways to challenge, invalidate or otherwise circumvent our patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

If a product covered by our patents or patents exclusively licensed to us is approved, then when those of our patents and exclusively licensed patents covering that product expire, or if they are challenged and held to be invalid or otherwise circumvented before they expire, that product may be subject to generic competition.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of these trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired, and our business and competitive position would suffer.

We will market our company and our products using trademarks. In the United States, we have filed "intent-to-use" trademark applications for the names Rylomine and Dyloject that have been allowed. If we do not market products under those trademarks within a specified period of time (initially six months, with extensions of up to three years from the date of allowance), we may not be able to register those trademarks. We have also filed "use-based" U.S. trademark applications for our name, our logo, and our name and logo together. If any of these applications do not result in registration of the applicable trademark, we may not be able to use that trademark in commerce, and we may incur additional, unanticipated costs to identify and register new trademarks in lieu of the trademarks that are included in the pending applications.

**If we infringe the rights of third parties, we could be prevented from selling our products, forced to pay damages, and incur substantial costs in defending litigations.**

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs, and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

**We may be exposed to liability claims associated with the use of hazardous materials and chemicals.**

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that the safety procedures of our manufacturers and distributors for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, the risk of accidental injury or contamination from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

**We may become subject to substantial product liability claims for which we have limited insurance, and may be required to limit commercialization of our products in response to product liability lawsuits.**

The testing and marketing of medical products entail an inherent risk of product liability. Although side effects from clinical trials thus far have been generally limited to symptoms known to be associated with these well-established medications, such as dysphoria (a feeling of malaise), and nausea, we may be held liable if any more serious adverse reactions from the use of our product candidates occurs. Our product candidates involve new methods of delivery for potent drugs that require greater precautions to prevent unintended use, especially since they are designed for patients' easy self-use rather than for administration by medical professionals. For example, the FDA may require us to develop a comprehensive risk management program for our product candidates to reduce the risk of improper patient selection, diversion and abuse. The failure of these measures could result in harmful side effects or death. As a result, consumers, regulatory agencies, pharmaceutical companies or others might make claims against us. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry clinical trial insurance but do not carry product liability insurance. We, or any corporate collaborators, may not be able to obtain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises.

**Risks Related to Management**

**We may not successfully manage our growth, thereby preventing achievement of our business plan.**

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational, and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems, and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

**We rely on key executive officers and scientific and medical advisors whose knowledge of our business and technical expertise would be difficult to replace.**

We are highly dependent on Daniel B. Carr, MD, our Chief Executive Officer and Chief Medical Officer, as well as other executive officers, including Curtis Wright, our Vice President, Risk Management and Regulatory Affairs. We do not have "key person" life insurance policies for any of our officers. We do not have employment agreements with any person other than with Dr. Carr, Stephen J. Tulipano, our Chief Financial Officer, and David B. Bernstein, our Secretary, General Counsel and Chief IP Counsel. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development and clinical testing, loss of customers and sales, if any, and diversion of management resources, which could adversely affect operating results.

In addition, we rely on members of our scientific advisory board and consultants to assist us in formulating our research and development strategy. All of the members of our scientific advisory board and our clinical advisors have other jobs and commitments and may be subject to non-disclosure obligations that may limit their availability to work with us.

## Market Risks

**The market price of our common stock may fluctuate significantly, which may cause certain investors to avoid purchasing our shares.**

Since July 20, 2006, our common stock has been listed on The American Stock Exchange Inc. (the "ASE") under the symbol "JAV." The market price for our common stock may fluctuate significantly in response to factors, some of which are beyond our control, such as:

- announcement of new products or product enhancements by us or our competitors;
- results of the testing and regulatory approval of our products;
- developments concerning intellectual property rights and regulatory approvals and concerns;
- quarterly variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- developments in our industry; and
- general market conditions and other factors, including factors unrelated to our own operating performance.

**There has been a limited market for our common stock, which may accelerate price swings.**

Recent history relating to the market prices of public companies indicates that, from time to time, there may be periods of extreme volatility in the market price of our common stock. As our common stock only recently began trading on the ASE, there is no assurance that the trading market will become more active. Prior thereto, our common stock had been traded on the OTC Bulletin Board with an inactive market and the bid and asked prices for our common stock having fluctuated significantly on low trading volumes. Since December 2004 the market price of our common stock has ranged from \$1.90 to \$5.67 per share. Because of the limited trading volume in our common stock, holders may be unable to sell their shares of our common stock when or at prices they desire. Moreover, the inability to sell shares in a declining market because of such illiquidity or at a price holders desire may substantially increase their risk of loss.

**The American Stock Exchange imposes listing standards on our common stock that we may not be able to fulfill, thereby leading to a possible delisting of our common stock.**

As a listed ASE company, we are subject to ASE rules covering among other things, certain major corporate transactions, the composition of our Board of Directors and committees thereof, minimum stockholders equity, and the maintenance of the market price of our common stock. We had not previously been subject to similar regulations. The failure to meet these or other ASE requirements may result in the delisting of our common stock from the ASE, which could adversely affect the liquidity and market price thereof.

### Risks Related to our Common Stock

**We have not previously paid dividends on our common stock and we do not anticipate doing so in the foreseeable future.**

We have not in the past paid any dividends on our common stock and do not anticipate that we will pay any dividends on our common stock in the foreseeable future. Any future decision to pay a dividend on our common stock and the amount of any dividend paid, if permitted, will be made at the discretion of our board of directors.

**We may issue shares of preferred stock that have greater rights than our common stock.**

We are permitted by our certificate of incorporation to issue up to 5,000,000 shares of preferred stock. We can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from our common stockholders or other security holders. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation rights and may have greater voting rights than our common stock.

**A significant number of shares of our common stock are subject to options and warrants, and we may issue additional options and warrants in the future. The issuance of shares of common stock upon the exercise of these options and warrants will dilute the interests of other security holders and may depress the price of our common stock.**

As of March 1, 2007, there were 40,463,081 shares of common stock outstanding. As of such date, there were vested outstanding options to purchase up to 2,915,632 shares of common stock granted under the Javelin 2005 Omnibus Stock Incentive Plan (the "Incentive Plan"), unvested outstanding options to purchase up to 3,332,194 shares of common stock granted under the Incentive Plan, and outstanding

warrants to purchase up to 2,715,287 shares of common stock. There were also outstanding as of March 1, 2007 options to purchase up to 1,184,058 shares of common stock granted outside of the Incentive Plan. In addition, we may issue additional options and warrants from time to time to provide compensation to our employees, officers, directors and consultants under our stock option plans, and to finance our operations. The issuance, perceived issuance, or exercise of warrants or options will have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

**Provisions in our certificate of incorporation and provisions under Delaware law may inhibit a takeover of our Company.**

Under our certificate of incorporation, our board of directors is authorized to issue shares of our common or preferred stock without the approval of our stockholders, subject to certain ASE regulations. Issuance of these shares could make it more difficult for third parties to acquire us without the approval of our board of directors as more shares would have to be acquired to gain control. Also, Delaware law imposes restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock. These provisions may deter hostile takeover attempts that could result in an acquisition of us that could have been financially beneficial to our stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

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

**ITEM 2. PROPERTIES**

Our principal executive offices consist of approximately 10,553 square feet of leased space at 125 CambridgePark Drive, Cambridge, MA under a six-year lease expiring in 2012 at an annual base rental in the first year of approximately \$185,000 and an annual base rental in the remaining years of approximately \$282,000, with 3.9% annual escalations beginning after the second year. As of November 30, 2006, we vacated our office in New York, NY upon termination of the lease. In August 2006, we entered into a lease of approximately 2,500 square feet in Lake Success, NY, to support our manufacturing group, under a lease expiring in 2009 at an annual base rental of approximately \$57,500, with 3.5% annual escalation. We believe these premises are sufficient for our current needs.

**ITEM 3. LEGAL PROCEEDINGS**

From time to time, we are involved in disputes and legal proceedings arising in the ordinary course of business. As of December 31, 2006, we were not a party to any material legal proceedings nor are we aware of any circumstance that may reasonably lead a third party to initiate material legal proceedings against us.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2006.

**PART II.**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Principal Market and Market Prices**

Our common stock has traded on the American Stock Exchange (ASE) since July 20, 2006 under the symbol JAV, having previously traded in the over-the-counter market on the OTC Electronic Bulletin Board (OTCBB) under the symbol JVPH from September 7, 2005 (having been traded under the symbol ITRD prior thereto). The following table sets forth for the indicated periods the high and low sales price or bid price, as applicable, of our common stock for the two fiscal years ended December 31, 2006, as reported on the ASE and OTCBB. With respect to the OTCBB, such quotations are based on quotations between dealers, and do not reflect retail mark-up, mark-down or commissions, and may not necessarily represent actual transactions.

Fiscal Period	Fiscal Year Ended 12/31/06		Fiscal Year Ended 12/31/05	
	High	Low	High	Low
First Quarter	\$ 4.35	\$ 2.95	\$ 4.20	\$ 2.50
Second Quarter	4.15	3.20	3.02	1.90
Third Quarter	3.92	3.00	3.85	2.30
Fourth Quarter	5.67	2.66	3.49	1.95

**Approximate Number of Holders of Our Common Stock**

On March 1, 2007, there were approximately 212 stockholders of record of our common stock, excluding record holders of IDDS common stock who have not yet exchanged the certificates for their IDDS shares for our common stock. In addition, a number of shares of common stock are held in street or nominee name, so it is believed that there are a substantial number of additional beneficial owners of our common stock.

**Dividends**

We have not paid any cash dividends on our common stock in the past, and we do not anticipate doing so in the foreseeable future. All cash resources are expected to be invested in our business.

**Transfer Agent**

American Stock Trust & Transfer Company, New York, New York, is the transfer agent for our common stock.

**Securities Authorized For Issuance Under Equity Compensation Plans**

**Equity Compensation Plan Information**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	5,374,477	\$ 2.88	2,125,523
Equity compensation plans not approved by security holders	1,184,058	\$ 3.87	0
<b>Total:</b>	<b>6,558,535</b>	<b>\$ 3.06</b>	<b>2,125,523</b>

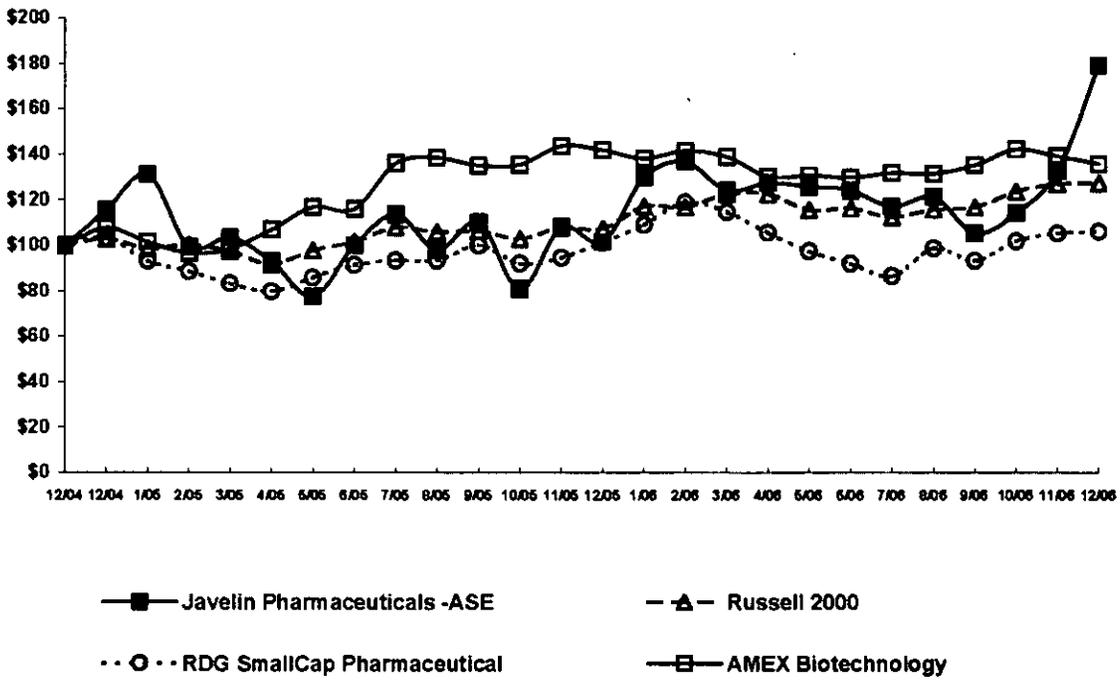
**Performance Graph**

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

The graph below shows a comparison of cumulative total return on our common stock to the cumulative return on The Russell 2000 Index, the RDG Small Cap Pharmaceutical Index and the AMEX Biotechnology Index since December 7, 2004. The performance graph is being shown only from December 7, 2004 because Intrac, Inc., our predecessor, had been a "shell" corporation without operations and very limited trading of its common stock until the December 7, 2004 closing of the merger between Intrac and IDDS, which had been a private company. The Performance Graph assumes reinvestment of dividends, where applicable. The stock performance shown on the graph below is based on historical data and is not indicative of, or intended to forecast, the possible future performance of our common stock.

**COMPARISON OF 2 YEAR CUMULATIVE TOTAL RETURN\***

Among Javelin Pharmaceuticals, Inc., The Russell 2000 Index,  
The RDG Smallcap Pharmaceutical Index And The AMEX Biotechnology Index



\*\$100 invested on 12/7/04 in stock or on 11/30/04 in an index-including reinvestment of dividends.  
Fiscal Year ending December 12<sup>th</sup>.

**ITEM 6. SELECTED FINANCIAL DATA**

The selected financial data presented below, which has been derived from our audited consolidated financial statements for the fiscal years 2002-2006, should be read in conjunction with Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and the accompanying consolidated financial statements and related notes included in this Annual Report. The following table sets forth selected consolidated financial data as of and for the years in the five year period ended December 31, 2006. All share and per share amounts have been adjusted to reflect the 1.018 per share exchange ratio in the December 2004 reverse merger between Intrac and IDDS, and the 1.016-for-1 stock split on March 12, 2002. Historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,					Cumulative from February 23, 1998 (Inception) to December 31, 2006
	2006	2005	2004	2003	2002	
	(In thousands, except per share data)					
<b>Statement of Operations Data:</b>						
Revenues:						
Government grants and contracts	\$ 842	\$ 1,548	\$ 837	\$ 1,102	\$ 287	\$ 5,804
Operating expenses:						
Research and development	10,854	7,213	4,806	2,217	2,415	57,218
Selling, general and administrative	9,609	5,222	2,703	2,013	5,975	29,731
Depreciation and amortization	61	44	32	24	13	179
Total operating expenses	20,524	12,479	7,541	4,254	8,403	87,127
Operating loss	(19,682)	(10,931)	(6,704)	(3,152)	(8,116)	(81,322)
Other income	601	—	4	—	—	605
Interest expense	—	—	(356)	(17)	(3)	(944)
Interest income	1,283	319	9	14	60	2,223
Other income (expense)	1,884	319	(343)	(3)	57	1,884
Net loss	(17,798)	(10,612)	(7,047)	(3,155)	(8,059)	(79,438)
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock.	—	—	—	—	—	(3,559)
Net loss attributable to common stockholders	\$ (17,798)	\$ (10,612)	\$ (7,047)	\$ (3,155)	\$ (8,059)	\$ (82,998)
Net loss per share attributable to common stockholders:						
Basic and diluted	\$ (0.44)	\$ (0.38)	\$ (0.64)	\$ (0.32)	\$ (0.81)	
Weighted average shares	40,180	27,831	10,937	9,918	9,917	

	As of December 31,				
	2006	2005	2004	2003	2002
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 9,273	\$ 33,307	\$ 14,783	\$ 3,151	\$ 2,172
Short term marketable securities	11,462	—	—	—	—
Working capital	17,885	32,988	12,173	2,366	1,496
Convertible preferred stock	—	—	—	23,183	18,795
Total assets	21,441	34,439	15,156	3,510	2,903
Stockholders equity (deficit)	18,232	33,202	12,342	(20,673)	(17,689)

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

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this Annual Report. This discussion includes forward-looking statements that involve risks and uncertainties. Operating results are not necessarily indicative of results that may occur in future periods.

### Forward Looking Statements

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

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

### Overview

We are a specialty pharmaceutical company that applies proprietary technologies to develop new products and improved formulations of existing drugs that target current unmet and underserved medical needs primarily in the pain management market. Our product candidates are designed to offer enhanced pain relief, fewer adverse side effects and faster relief of pain compared to other currently available treatments. We have three late stage product candidates in clinical development: Dyloject™ (diclofenac sodium injectable), PMI-150 (intranasal ketamine) and Rylomine™ (intranasal morphine).

We have devoted substantially all of our resources since we began our operations in February 1998 to the development of proprietary pharmaceutical products for the treatment of pain. We have not generated any revenues from product sales. Since our inception, we have incurred an accumulated net loss attributable to our common stockholders of approximately \$79.4 million through December 31, 2006, excluding approximately \$3.6 million of a deemed dividend. These losses have resulted principally from costs incurred in research and development activities, including acquisition of technology rights, general and administrative expenses, and most recently, sales and marketing expenses. Research and development activities include salaries, benefits and stock based compensation for our research, development and manufacturing employees, costs associated with nonclinical and clinical trials, process development and improvement, and clinical and commercial scale manufacturing. Selling, general and administrative related costs include salaries, benefits and stock based compensation for employees, temporary and consulting expenses, and costs associated with our pre-launch selling and marketing activities in the UK.

On September 7, 2005, we completed a merger with Intrac, Inc. ("Intrac"), a Nevada corporation, for the purpose of migrating the Intrac corporate entity to Delaware, at which time Javelin Pharmaceuticals, Inc. ("Javelin") continued the business conducted by Intrac. Javelin was incorporated in July 2005 in the State of Delaware by Intrac.

On December 6, 2004, we completed a reverse merger transaction with Innovative Drug Delivery Systems, Inc. ("IDDS"), whereby Intrac Merger Sub, Inc., a newly-formed wholly-owned subsidiary of Intrac merged with and into IDDS, with IDDS as the surviving corporation and a wholly-owned subsidiary of Intrac. In consideration for their shares of IDDS, the former stockholders of IDDS received approximately 95.5% of the outstanding common stock of Intrac. Following the merger, the executive officers and directors of IDDS became the executive

officers and directors of Intrac. For accounting purposes, the merger was treated as a reverse acquisition with IDDS as the acquirer and Intrac as the acquired party. Therefore, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of IDDS. The merger did not have any significant effects on our assets or liabilities or on our results of operations subsequent to the date of the merger.

Since our inception, we have incurred approximately \$57.2 million of research and development costs. The major research projects undertaken by us include the development of Dyloject™, PMI-150 and Rylomine™. Total research and development costs incurred to date for each of these products was approximately \$9.9 million, \$11.9 million and \$15.2 million, respectively. In addition, we incurred approximately \$1.6 million of research and development costs since inception that do not relate to our major research projects, and we incurred a charge of approximately \$18.6 million related to the merger of IDDS with Pain Management, Inc. and the related acquisition of a licensing agreement in 1998.

For various reasons, many of which are outside our control, including timing and results of our clinical trials, obtaining regulatory approval and our dependence on third parties, we cannot estimate the total remaining costs to be incurred to commercialize our products, nor is it possible to estimate when, if ever, any of our products will be approved by regulatory agencies for commercial sale. In addition, we may experience adverse results in the development of our products, which could result in significant delays in obtaining approval to sell our products, additional costs to be incurred to obtain regulatory approval or failure to obtain regulatory approval. If any of our product candidates were to experience setbacks, it would have a material adverse effect on our financial position and operating results. Even if we successfully complete development and obtain regulatory approval of one or more of our products, failure of physicians and patients to accept our products as a safe, cost-effective alternative compared to existing products would have a material adverse effect on our business.

Our financial statements have been prepared on a going-concern basis, which assumes realization of assets and settlement of liabilities in the ordinary course of business. We have limited capital resources, significant net operating losses and negative cash flows from operations since inception and expect these conditions to continue for the foreseeable future. In addition, it is anticipated that we likely will not generate significant revenues from product sales during the year ending December 31, 2007. Although we believe that our existing cash resources will be sufficient to support the current operating plan at least through June 30, 2007, we will need additional financing to support our operating plan thereafter or we will need to modify our operating plan accordingly. We may raise additional funds through the private and/or public sale of our equity securities. We may also seek to raise capital through collaborative arrangements with corporate sources or other sources of financing. There can be no assurance that such additional financing, if at all available, can be obtained on terms reasonable to us. If sufficient funds are not available, we will need to postpone or discontinue future planned operations and projects.

## **Results of Operations**

**Revenues.** With the exception of revenues derived from government grants and contracts, we have generated no operating revenues since our inception and do not expect significant operating revenues for the foreseeable future. In October 2000, we received a grant of \$1.2 million from the U.S. Department of Defense ("DOD"). In May 2003, the DOD extended funding of the development of PMI-150 by awarding us a \$4.3 million contract. The DOD reimburses us for certain research and development costs related to the PMI-150 development program which can fluctuate from period to period. The DOD contract was the sole source of contract and grant revenue. The DOD contract is billed monthly as costs are incurred.

Contract revenue decreased from approximately \$1.5 million for the year ended December 31, 2005 to approximately \$842,000 for the year ended December 31, 2006. The decrease is attributable to decreased activity associated with expenditures billable to the DOD contract.

Contract revenue increased from approximately \$837,000 for the year ended December 31, 2004 to approximately \$1.5 million for the year ended December 31, 2005. The increase is attributable to increased activity associated with expenditures billable to the DOD contract.

As of December 31, 2006, we have no additional funds available for reimbursement from the DOD grant. Additionally, we do not expect to generate significant revenue from sales of product in 2007.

**Research and Development Expenses.** Research and development expenses consist primarily of salaries, stock based compensation and related expenses for personnel, materials and supplies used to develop and manufacture our product candidates. Other research and development expenses include compensation paid to consultants and outside service providers to run the clinical trials. We expense research and development costs as incurred. We expect that we will continue to incur significant research and development expenses in the future as our three product candidates proceed with pivotal clinical trials and progress through the later stages of product development towards commercialization. Research and development expenses may fluctuate from period to period due to the timing and nature of clinical trial expenditures and regulatory filings.

Research and development expenses increased from approximately \$7.2 million for the year ended December 31, 2005 to \$10.9 million for the year ended December 31, 2006. The increase in research and development expenses resulted from the advancement of each of our three product candidate development programs. Research and development salaries, temporary labor, and benefits increased by approximately \$1.7 million as compared to the same period of the prior year. The increase was due primarily to the addition of full time personnel and

recording stock based compensation in accordance with the adoption of SFAS 123(R) in 2006. Expenses associated with clinical trials, including lab fees, increased by approximately \$1.1 million. Expenses associated with manufacturing and process development increased by \$736,000 compared to the same period of the prior year. Milestone expenses increased from approximately \$200,000 for the year ended December 31, 2005 to \$300,000 for the year ended December 31, 2006.

Dyloject™ product development costs increased from approximately \$3.0 million for the year ended December 31, 2005 to \$3.5 million for the year ended December 31, 2006. In May 2006, we commenced treatment of the first patient in our Phase III clinical program. This pivotal U.S. study will enroll 360 patients with moderate-to-severe postoperative pain following abdominal surgery. In 2005, we completed a 155 patient European phase II/III pivotal study and had completed and submitted the MAA (marketing authorization application) to the MHRA. Also in 2005, we initiated a 353 patient dose-response U.S. phase IIb clinical study and completed patient enrollment by the year ended December 31, 2005. Costs associated with manufacturing the clinical drug supply and the ongoing Dyloject™ stability program were approximately \$599,000 for the year ended December 31, 2006.

PMI-150 product development costs increased from \$1.7 million for the year ended December 31, 2005 to \$2.6 million for the year ended December 31, 2006. Clinical trial expenses, including labs, data management and monitoring, for the year ended December 31, 2006 were approximately \$588,000 and were associated with ongoing studies for our PMI-150 product candidate. In 2005 we completed the PMI-150 bioequivalency program and initiated a U.S. phase II study for which we completed enrollment by December 2005. Clinical manufacturing expenses were approximately \$960,000 for the year ended December 31, 2006. Milestone payments were not paid during 2006.

Rylomine™ product development costs increased from \$2.5 million for the year ended December 31, 2005 to \$4.8 million for the year ended December 31, 2006. Clinical trial expenses, including labs, site fees, data management and monitoring, were approximately \$3.3 million for the year ended December 31, 2006. In May 2006, we initiated a Phase III clinical study of Rylomine™. This pivotal U.S. study will enroll 256 patients with moderate-to-severe postoperative orthopedic pain. In 2006 clinical manufacturing costs of \$481,000 were associated primarily with the drug supply and the ongoing formal stability program. In 2005, we initiated a 187 patient multi-center dose-response phase IIb clinical study and by December 2005 we had completed patient enrollment and analysis of the data. Clinical manufacturing and regulatory expenses were approximately \$452,000 and \$121,000, respectively for the year ended December 31, 2005.

Research and development expenses increased from approximately \$4.8 million for the year ended December 31, 2004 to \$7.2 million for the year ended December 31, 2005. Research and development salaries, temporary labor and benefits increased by approximately \$575,000 as compared to the same period of the prior year. The increase was due primarily to the addition of full time personnel. Expenses associated with clinical trials and clinical manufacturing and process development increased by approximately \$1.9 million and \$319,000, respectively as compared to the same period of the prior year. Milestone expenses decreased from approximately \$1.0 million for the year ended December 31, 2004 to \$200,000 for the year ended December 31, 2005.

Dyloject™ product development costs increased from approximately \$1.6 million for the year ended December 31, 2004 to \$3.0 million for the year ended December 31, 2005. By July 2005, we completed a 155 patient European phase II/III pivotal study and by September 2005 had completed and submitted the MAA (marketing authorization application) to the MHRA. Regulatory costs, milestone fees payable to a licensor and European regulatory filing fees associated with the MAA filing were approximately \$470,000, \$200,000 and \$42,000, respectively for the year ended December 31, 2005. Also in 2005 we initiated a 353 patient dose-response U.S. phase IIb clinical study and completed patient enrollment by the year ended December 31, 2005. Clinical trial costs increased to \$1.5 million for the year ended December 31, 2005 as the Dyloject™ program advanced toward phase III in the U.S. and product filing in Europe. Costs associated with the clinical drug supply and the ongoing Dyloject™ stability program were approximately \$381,000 for the year ended December 31, 2005.

PMI-150 product development costs decreased from \$2.6 million for the year ended December 31, 2004 to \$1.7 million for the year ended December 31, 2005. Clinical trial expenses for the year ended December 31, 2005 were approximately \$751,000 and were associated with the ongoing phase II program. Clinical manufacturing and regulatory expenses were approximately \$471,000 and \$80,000, respectively for the year ended December 31, 2005. Milestone payments decreased by approximately \$1.0 million as compared to the same period of the prior year.

Rylomine™ product development costs increased from \$0.6 million for the year ended December 31, 2004 to \$2.5 million for the year ended December 31, 2005. Clinical trial expenses were approximately \$1.4 million for the year ended December 31, 2005. In 2005, we initiated a 187 patient multi-center dose-response phase IIb clinical study and by December 2005 we had completed patient enrollment and analysis of the data. Clinical manufacturing and regulatory expenses were approximately \$452,000 and \$121,000, respectively for the year ended December 31, 2005. In 2005 clinical manufacturing costs were associated primarily with the ongoing formal stability program and the development and validation of test methods in support of regulatory submissions. Regulatory expenses were associated primarily with the preparation for future FDA regulatory meetings.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses consist primarily of salaries, stock based compensation and other related costs for personnel in executive, finance, accounting, information technology and human resource functions. Other costs include facility costs and professional fees for legal and accounting services. We expect selling, general and administrative expenses to increase primarily as a result of increased sales and marketing costs associated with the potential launch of Dyloject in the UK, and as we expand and improve our administrative infrastructure.

Selling, general and administrative expenses increased from approximately \$5.2 million for the year ended December 31, 2005 to \$9.6 million for the year ended December 31, 2006. Salary, stock based compensation and benefits expense increased by approximately \$2.9 million due to an increase in full time headcount and stock based compensation in accordance with our adoption of SFAS 123(R) in 2006. Non-cash compensation decreased by approximately \$719,000 from amortization of deferred stock option expense and warrant expense. During 2006 we incurred higher legal and patent fees of approximately \$427,000 and \$123,000, respectively, primarily related to defending an arbitration decided in our favor in September 2006, maintenance, protection and expansion of our intellectual property, and costs incurred for listing on the American Stock Exchange in July 2006. Our third party consulting costs increased by nearly \$529,000 in 2006 primarily due to additional support required to document and maintain internal controls to ensure Sarbanes Oxley compliance. Additionally, we incurred higher selling and marketing costs of approximately \$1.0 million related to pre-launch sales and marketing consulting and market research in preparation for our potential launch of Dyloject in the near future.

General and administrative expenses increased from approximately \$2.7 million for the year ended December 31, 2004 to \$5.2 million for the year ended December 31, 2005. Salary and benefit expense increased by approximately \$654,000 due to an increase in full time headcount that was partially offset by a decrease of approximately \$298,000 in consulting and temporary headcount expense. Liquidated damages associated with our December 2004 financing totaled approximately \$468,000 for the year ended December 31, 2005. Non-cash compensation increased to approximately \$388,000 from amortization of deferred stock option expense and warrant expense. Due to activities associated with being a public company, we incurred higher accounting, investor/public relations, legal, travel and insurance expenses of approximately \$219,000, \$213,000, \$162,000, \$150,000 and \$146,000, respectively. Costs associated with recruitment of personnel and relocation of existing personnel to our Cambridge office increased by \$193,000 and \$80,000, respectively. Rent, office and communication expense increased due to the costs associated with opening our Cambridge, Massachusetts corporate office by \$58,000, \$25,000, and \$23,000, respectively. Website fees increased by \$10,000 associated with the redesign and launch of our new web site in 2005.

**Interest Income.** Interest income consists of interest earned on our cash, cash equivalents and short term marketable securities available for sale. Interest income increased from approximately \$320,000 for the year ended December 31, 2005 to approximately \$1.3 million for the year ended December 31, 2006 due to higher average invested balances of cash, cash equivalents and short term investments in 2006.

Interest income increased from approximately \$9,000 for the year ended December 31, 2004 to approximately \$320,000 for the year ended December 31, 2005 due to higher average invested balances of cash and cash equivalents in 2005.

**Interest Expense.** Interest expense historically has consisted of interest incurred on loans. There was no significant interest expense for the years ended December 31, 2006 and 2005. For the year ended December 31, 2004, interest expense consisted primarily of the interest charges of approximately \$315,000 associated with a Debenture Note that was issued and retired in 2004.

**Other Income.** In February 2006, we settled litigation with West Pharmaceutical Services, Inc. ("West") regarding West's assignment of certain license agreements to Archimedes Pharma Limited ("Archimedes") as part of the sale West's Drug Delivery business to Archimedes. Under the terms of the settlement, on March 1, 2006 West paid us approximately \$600,000 to resolve all claims, and the parties exchanged mutual releases. The amount received from West in 2006 is included in other income for the year ended December 31, 2006.

### **Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through the private placement of our equity securities, debt financings and grant revenue primarily from the U.S. Department of Defense. We may raise additional funds through the private and/or public sale of our equity securities. We may also seek to raise capital through collaborative arrangements with corporate sources or other sources of financing. We intend to continue to use the proceeds from these sources to fund ongoing research and development activities, activities related to potential future commercialization, capital expenditures, working capital requirements and other general purposes. As of December 31, 2006, we had cash, cash equivalents and short term investments of approximately \$20.7 million, compared to \$33.3 million as of December 31, 2005.

On November 7, 2005 we closed a private placement consisting of the sale of approximately 14.2 million shares of our common stock and 711,111 warrants for net proceeds of approximately \$29.8 million. In December 2004, we raised approximately \$18.1 million through the sale of approximately 6.1 million shares of our common stock at \$2.95 per share in a private placement. Although we believe that our existing cash resources will be sufficient to support the current operating plan at least through June 30, 2007, we will need additional financing to support our operating plan thereafter or we will need to modify our operating plan accordingly. We may raise additional funds through the private and/or public sale of our equity securities. We may need to raise additional funds to meet long-term planned goals. On February 6, 2007, we filed with the SEC a Registration Statement on Form S-3 under the Securities Act, which became effective on February 12, 2007. This registration statement allows us, from time to time, to offer and sell shares, and warrants to purchase shares, of our common stock, but

not to exceed \$50 million. To date, we have not issued any additional shares or warrants under this registration statement. There can be no assurance that additional financing, if at all available, can be obtained on terms acceptable to us. If we are unable to obtain such additional financing, future operations will need to be scaled back or discontinued.

As a development stage enterprise, our primary efforts, to date, have been devoted to conducting research and development, raising capital, forming collaborations and recruiting staff. We have limited capital resources and revenues, have experienced an \$83.0 million net loss attributable to our common stockholders and have had negative cash flows from operations since inception. These losses have resulted principally from costs incurred in research and development activities, including acquisition of technology rights, increasing costs related to potential future commercialization of our product candidates, and general and administrative expenses. As of December 31, 2006, we have paid an aggregate of \$5.6 million and \$2.2 million in cash since inception to West Pharmaceutical and Shimoda Biotech (Proprietary) Ltd., respectively, pursuant to agreements that we have entered into with these entities. We expect to incur additional operating losses until such time as we generate sufficient revenue to offset expenses, and we may never achieve profitable operations.

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

- Conduct commercialization activities in support of Dyloject™ product launch including pre-launch planning, development of market plans, pricing and reimbursement application, development of regional sales and marketing capabilities;
- Conduct remaining nonclinical programs, including carcinogenicity studies to support both PMI-150 and Rylomine™ regulatory submission and label extensions;
- Conduct clinical programs, including phase III clinical trials to support regulatory submissions and label extensions of our product candidates;
- Continue to support Good Manufacturing Practices (“GMP”) drug supply requirements of our nonclinical and clinical trials; complete formal stability testing, analytical development, methods development, specification development and commercial scale-up;
- Maintain, protect and expand our intellectual property;
- Develop expanded internal infrastructure; and
- Hire additional personnel.

#### **Cash used in operating activities**

From inception through December 31, 2006, net cash used in operating activities was approximately \$49.0 million. Net cash used in operating activities increased to approximately \$12.5 million for the year ended December 31, 2006 from approximately \$11.3 million for the year ended December 31, 2005.

Net cash from operating activities for the year ended December 31, 2006 consists primarily of our net loss of \$17.8 million. The increase in net cash used for operating activities was due primarily to higher cash outflows associated with an increase in selling, general and administrative expenses and research and development activity in 2006. Significant increases were directly related to salaries, benefits and infrastructure costs related to the addition of several new personnel, advancing our research and development clinical trials for each of our product candidates, and increased pre-launch planning and development costs as we approach potential commercialization of Dyloject. Operating cash flows differ from net income as a result of non-cash charges or changes in working capital, primarily our non-cash stock based compensation expenses of approximately \$2.8 million. Also in 2006, our outstanding payables increased by approximately \$1.9 million, while our outstanding receivable from the DOD decreased by approximately \$460,000 for the year ended December 31, 2006.

Net cash used in operating activities increased to approximately \$11.3 million for the year ended December 31, 2005 from approximately \$4.5 million for the year ended December 31, 2004.

The increase in net cash used for operating activities was due primarily to higher cash outflows associated with an increase in general and administrative and research and development activity in 2005. Further contributing to the increase were non-cash compensation expenses of approximately \$346,000 due to amortization of deferred stock options and warrants, as well as the \$373,000 non-cash expense associated with common stock issued to private placement investors for liquidated damages. Also in 2005, our outstanding payables decreased by approximately \$1.1 million. Our outstanding receivable from the DOD increased by approximately \$458,000 for the year ended December 31, 2005.

#### **Cash used in investing activities**

From inception through December 31, 2006, net cash used in investing activities was approximately \$11.8 million, primarily related to the net purchases of short term marketable securities available for sale. Proceeds from our 2005 financing were invested in marketable securities in

the first quarter of 2006, primarily in short term marketable securities. Gross purchases were approximately \$23.3 million, while gross proceeds from sales and maturities were approximately \$11.8 million. From inception to December 31, 2006, capital expenditures have not been material resulting from our use of contract manufacturing facilities. We expect that cash used for investing activities in 2007 will fluctuate based on the future funding and the need to utilize our current investments for operations.

From inception through December 31, 2005, net cash used in investing activities was approximately \$279,000, primarily due to the acquisition of manufacturing equipment, furniture and fixtures and office equipment. Net cash used in investing activities was approximately \$69,000 for the year ended December 31, 2005 compared to \$119,000 in 2004.

#### Cash provided by financing activities

From inception through December 31, 2006, net cash provided by financing activities was approximately \$70.2 million. For 2006, net cash from financing activities related only to proceeds of approximately \$10,000 from the exercise of warrants. Net cash provided by financing activities increased to \$29.9 million for the year ended December 31, 2005 from approximately \$16.2 million for the year ended December 31, 2004. Our financing activities raised net cash of approximately \$29.8 million from the private placement of our common stock in 2005, and \$16.2 million from the private placement of our common stock in 2004.

#### Commitments

The following table summarizes our commitments as of December 31, 2006:

	Payments due by period				
	Total	< 1 Year	1-3 Years	3-5 Years	Beyond 5 Years
Operating leases (1)	\$ 1,733,539	\$ 294,988	\$ 676,913	\$ 626,428	\$ 135,210
Shimoda License Agreement (2)	5,800,000	2,000,000	3,800,000	—	—
Archimedes License Agreements (3)	5,000,000	—	5,000,000	—	—
	<u>\$ 12,533,539</u>	<u>\$ 2,294,988</u>	<u>\$ 9,476,913</u>	<u>\$ 626,428</u>	<u>\$ 135,210</u>

(1) We lease approximately 13,052 square feet of general office space in addition to small equipment leases.

(2) Under the license agreement with Shimoda Biotech, Ltd. we are obligated to make aggregate milestone payments of approximately \$5.8 million upon the occurrence of specified developmental milestones, which include the filing of an NDA with the FDA for Dyloject™, the approval of an NDA by the FDA and the first commercial sale of a licensed product and pay a royalty based upon our and our sublicensees' sales of products, which is subject to change, as noted.

(3) Under the license agreements with Archimedes Pharma Limited (assigned from West Pharmaceutical Services, Inc.), we may be required to pay an aggregate of \$5.0 million for research and development milestones if certain defined events occur, which include the first filing of a marketing authorization application with a regulatory agency, first approval of a marketing authorization application and the first commercial sale of a licensed product, which is subject to change, as noted.

The timing of the remaining milestones is dependent upon factors that are beyond our control, including our ability to recruit patients, the outcome of future clinical trials and any requirements imposed on our clinical trials by regulatory agencies. However, for the purpose of the above table, we have assumed that the payment of the milestones will occur between one to three years, from December 31, 2006.

#### Purchase Commitments

In February 2007, we entered into a Commercial Supply Agreement (the "Supply Agreement") with Precision Pharma Services, Inc. ("Precision"). The initial term of the Supply Agreement is two years, and it is renewable in one-year increments. Under the Supply Agreement, Precision agreed to manufacture our requirements for the supply of Dyloject™, in accordance with U.S. and E.U. good manufacturing practices. We committed to purchase at least \$7,650,000 worth of product during the two year period beginning on April 1, 2007.

Either party may terminate the Supply Agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable thirty (30) or ninety (90) day cure periods. Either party may also terminate the Supply Agreement upon sixty (60) days' prior written notice upon the occurrence of certain events involving the bankruptcy or insolvency of the other party, and the Supply Agreement shall automatically terminate upon the occurrence of certain events specified therein. Moreover, we may elect to terminate the Supply Agreement if Precision fails to meet its performance obligations regarding the manufacture of Dyloject™ in accordance with GMP, and under certain other conditions.

## Critical Accounting Policies and Significant Judgments and Estimates

**Revenue Recognition.** We have been awarded government grants and contracts from the U.S. Department of Defense (“DOD”) and the National Institutes of Health (the “NIH”), which are used to subsidize our research and development projects. The DOD reimburses us for certain research and development subproject costs related to the PMI-150 development program. DOD and NIH revenue is recognized as subsidized project costs for each period are incurred. Contract and grant revenue is derived from internal headcount expense and external contractual expense, both of which are highly dependent on the timing, order and relationship of individual reimbursable subprojects. Our grant submissions may fluctuate from period to period due to the timing and scope of these activities and the results of studies and clinical trials. As of December 31, 2006, we have utilized all available contract and grant funding.

**Research and Development Costs.** Since our inception, we have incurred approximately \$57.2 million of research and development costs. The major research projects undertaken by us include the development of Dyloject™, PMI-150 and Rylomine™. We expense all research and development costs as incurred for which there is no alternative future use. For various reasons, many of which are outside our control, including timing and results of our clinical trials, obtaining regulatory approval and dependence on third parties, we cannot estimate the total remaining costs to be incurred to commercialize our products, nor is it possible to estimate when, if ever, any of our products will be approved by regulatory agencies for commercial sale. In addition, we may experience adverse results in the development of our products, which could result in significant delays in obtaining approval to sell our products, additional costs to be incurred to obtain regulatory approval or failure to obtain regulatory approval. In the event any of our product candidates were to experience setbacks, it would have a material adverse effect on our financial position and operating results. Even if we successfully complete development and obtain regulatory approval of one or more of our products, failure of physicians and patients to accept our products as a safe, cost-effective alternative compared to existing products would have a material adverse effect on our business.

**Stock Based Compensation.** Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004) — Share-Based Payment, or SFAS 123(R). This Statement requires compensation cost relating to share-based payment transactions to be recognized in the financial statements using a fair-value measurement method. Under the fair value method, the estimated fair value of an award is charged against income on a straight-line basis over the requisite service period, which is generally the vesting period. We selected the modified prospective adoption method as prescribed in SFAS 123(R) and therefore, we have not restated our financial statements for prior periods. Under the modified prospective application, this Statement was applied to new awards granted in 2006, as well as to the unvested portion of previously granted stock option awards for which the requisite service had not been rendered as of January 1, 2006.

As a result of the adoption of SFAS 123(R), we recorded share-based compensation for 2006 as follows:

	<u>2006</u>
Research and development	\$ 924,218
Selling, general and administrative	1,898,721
Total impact on results of operations	<u>\$ 2,822,939</u>
Per share impact on results of operations	<u>\$ 0.07</u>

We have not capitalized any compensation cost. We recorded stock based compensation charges of \$479,442 related to the modification of certain stock option grants. No options were exercised during 2006 and no cash was used to settle equity instruments granted under our stock option plans. The adoption of SFAS 123(R) on January 1, 2006 did not result in any cumulative pre-tax adjustment related to compensation cost recorded in prior years under APB 25.

The fair value of the stock option grants were estimated on the date of grant using the Black-Scholes option valuation model that uses the following assumptions:

	<u>2006</u>
Expected volatility	80%
Expected life	5.0 years
Dividend yield	0%
Risk free interest rate	4.5% - 5.2%
Weighted average per share grant date fair value	\$2.50

Expected volatility is based upon implied volatility for our common stock and other factors. The expected term of stock options granted is derived from using the assumed exercise rates based on historical exercise patterns, and represents the period of time that options granted are expected to be outstanding. The risk free interest rate used is based upon the published U.S. Treasury yield curve in effect at the time of grant for instruments with a similar life. The dividend yield is based upon the fact that we have not historically granted dividends, and do not expect to in the future. Stock options granted prior to January 1, 2006 were valued based on the grant date fair value of those awards, using

the Black-Scholes option pricing model, as previously calculated for pro-forma disclosures under SFAS 123 — Accounting for Stock-based Compensation. Alternative estimates and judgments could yield materially different results.

#### **Income Taxes**

As of December 31, 2006, we had approximately \$45.0 million of net operating loss carryforwards available to offset future taxable income. These carryforwards will expire between 2020 and 2026. We have incurred operating losses since inception and have established valuation allowances equal to the total deferred tax assets due to the uncertainty with respect to achieving profitable operations in the future. Should the uncertainty regarding our ability to achieve profitable operations change in the future, we would reverse all or a portion of the valuation allowance, the effect of which could be material to our financial statements.

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

Certain warrants issued in conjunction with our common stock financing are equity linked derivatives and accordingly represent an off balance sheet arrangement. These warrants meet the scope exception in paragraph 11(a) of Statement of Financial Accounting Standards No. 133 - Accounting for Derivative Instruments and Hedging Activities, or SFAS 133, and are accordingly not accounted for as derivatives for purposes of SFAS 133, but instead included as a component of equity. See Footnote 6 to the financial statements and the Statement of Shareholders' Equity for more information.

#### **Recent Accounting Pronouncements**

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements" (SAB 108), which provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. We have adopted the provisions of SAB 108 in our annual financial statements for fiscal year 2006. The adoption of SAB 108 did not have a material impact on our consolidated financial statements.

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, "Fair Value Measurements" ("SFAS157"). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this Statement relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. We will be required to adopt the provisions of SFAS 157 beginning with our first quarter ending March 31, 2007. We do not believe that the adoption of the provisions of SFAS 157 will materially impact our consolidated financial statements.

In July 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires an entity to recognize the impact of a tax position in its financial statements if that position is more likely than not to be sustained on audit based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of fiscal year 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We do not anticipate that our adoption of FIN 48 will materially impact our consolidated financial statements.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### **Market Risk Related to Interest Rates and Foreign Currency**

We are exposed to market risks related to changes in interest rates and foreign currency exchange rates, however, we believe those risks to be not material in relation to our operations. We do not have any derivative financial instruments.

#### **Interest Rate Risk**

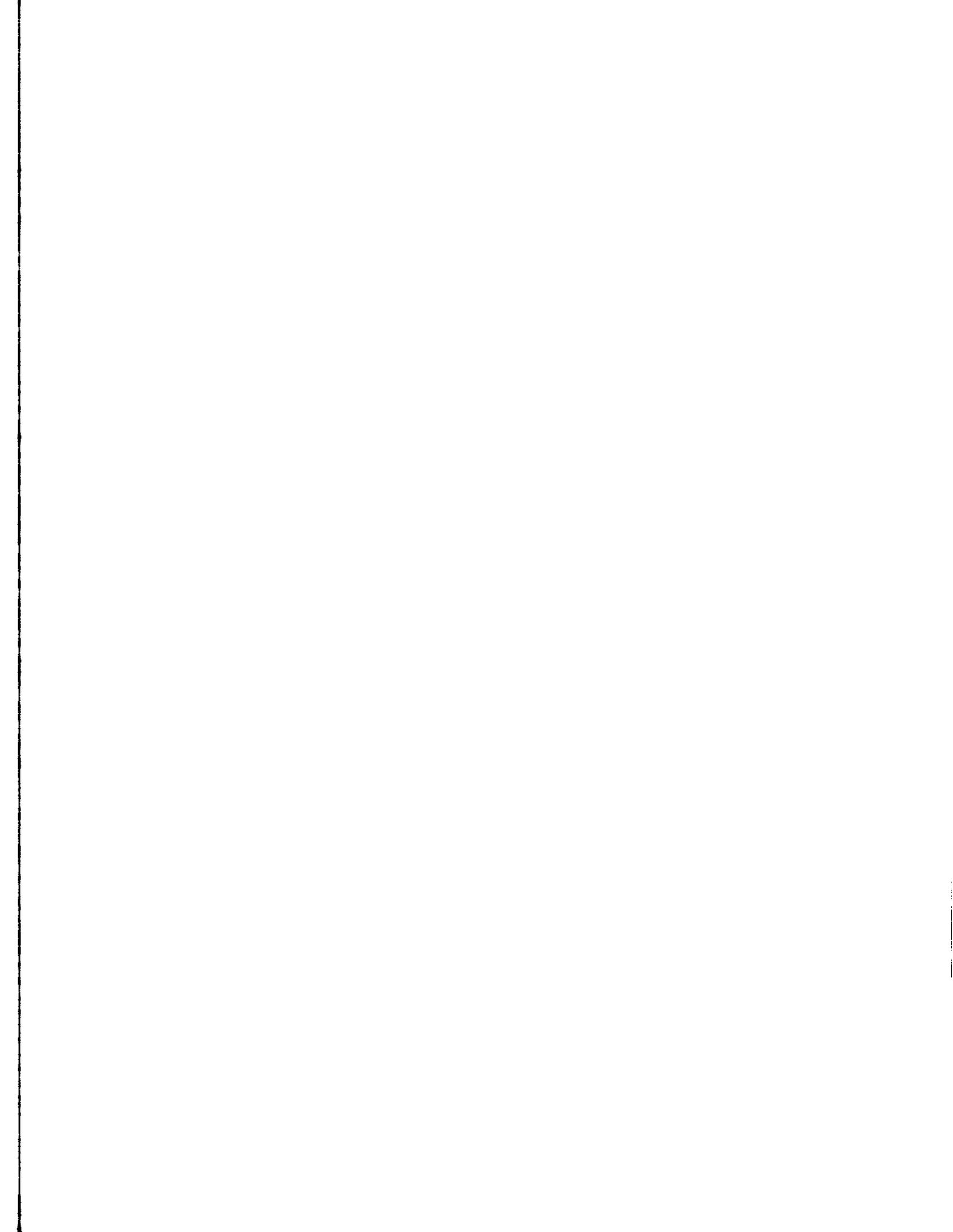
As of December 31, 2006, our cash included approximately \$6.4 million of money market securities, and \$11.5 million in short term available for sale marketable securities. Due to the short term duration of our investment portfolio, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio, therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

#### **Foreign Currency Exchange Risk**

All of our revenues are denominated in U.S. dollars and, as a result, we have relatively little exposure to foreign currency exchange risk with respect to current revenues. A minor portion of our research expenses are payable in foreign currency. We do not use forward exchange contracts to hedge exposures denominated in foreign currencies or any other derivative financial instruments for trading or speculative purposes. The effect of an immediate 10% change in exchange rates would not have a material impact on our future operating results or cash flows.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders  
Javelin Pharmaceuticals, Inc.  
Cambridge, Massachusetts

We have audited management's assessment, included in the accompanying *Management's Annual Report On Internal Control Over Financial Reporting*, that Javelin Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) (the "Company") maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Javelin Pharmaceuticals, Inc. and Subsidiary maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, Javelin Pharmaceuticals, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Javelin Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) and the related consolidated statements of operations, redeemable preferred stock and stockholders' equity (deficit), and cash flows as of, and for the year ended December 31, 2006, and the amounts included in the cumulative columns in the consolidated statements of operations and cash flows for the year then ended, and our report dated March 14, 2007 expressed an unqualified opinion.

/s/ McGladrey & Pullen, LLP  
Burlington, Massachusetts  
March 14, 2007

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Javelin Pharmaceuticals, Inc.

In our opinion, the consolidated balance sheet and the related statements of operations, changes in redeemable preferred stock and stockholders' equity (deficit) and cash flows present fairly, in all material respects, the financial position of Javelin Pharmaceuticals, Inc. (formerly Intrac, Inc.) and its subsidiary (a development stage enterprise) (the "Company") at December 31, 2005, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2005 and the cumulative period from February 23, 1998 (inception) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America. 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 of the statements 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.

As discussed in Note 2 to the financial statements, the Company has recurring losses and limited capital resources.

/s/ PricewaterhouseCoopers LLP  
New York, New York  
April 14, 2006

Javelin Pharmaceuticals, Inc. and Subsidiaries  
(A Development Stage Enterprise)  
Consolidated Balance Sheets

	December 31,	
	2006	2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,273,479	\$ 33,307,449
Short term marketable securities available for sale	11,461,674	—
Grant receivable	113,645	573,501
Prepaid expenses and other current assets	245,593	343,958
<b>Total current assets</b>	<b>21,094,391</b>	<b>34,224,908</b>
Fixed assets, at cost, net of accumulated depreciation	237,163	161,866
Other assets	109,223	52,188
<b>Total assets</b>	<b>21,440,777</b>	<b>34,438,962</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	3,151,379	1,207,626
Deferred revenue	—	19,522
Deferred lease liability	57,869	9,871
<b>Total current liabilities</b>	<b>3,209,248</b>	<b>1,237,019</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of December 31, 2006 and 2005, none of which are outstanding	—	—
Common stock, \$0.001 par value; 200,000,000 and 100,000,000 shares authorized as of December 31, 2006 and December 31, 2005, respectively; 40,409,421 and 40,404,977 shares issued and outstanding at December 31, 2006 and 2005, respectively.	40,409	40,404
Additional paid-in capital	97,634,546	95,355,368
Other comprehensive income (loss)	(5,117)	—
Unearned compensation	—	(553,756)
Deficit accumulated during the development stage	(79,438,309)	(61,640,073)
<b>Total stockholders' equity</b>	<b>18,231,529</b>	<b>33,201,943</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 21,440,777</b>	<b>\$ 34,438,962</b>

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

**Javelin Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Enterprise)**  
**Consolidated Statements of Operations**

	Year Ended December 31,			Cumulative from February 23, 1998 (inception) to December 31,
	2006	2005	2004	2006
Revenues:				
Government grants and contracts	\$ 842,171	\$ 1,547,753	\$ 836,841	\$ 5,804,824
Operating expenses:				
Research and development	10,854,116	7,212,801	4,806,073	57,217,713
Selling, general and administrative	9,608,598	5,222,104	2,702,673	29,730,593(1)
Depreciation and amortization	61,008	44,321	31,796	178,613
Total operating expenses	<u>20,523,722</u>	<u>12,479,226</u>	<u>7,540,542</u>	<u>87,126,919</u>
Operating loss	<u>(19,681,551)</u>	<u>(10,931,473)</u>	<u>(6,703,701)</u>	<u>(81,322,095)</u>
Other income (expense):				
Interest expense	(47)	(65)	(356,370)	(943,959)
Interest income	1,282,604	319,766	9,016	2,222,760
Other income	600,758	—	4,227	604,985
	<u>1,883,315</u>	<u>319,701</u>	<u>(343,127)</u>	<u>1,883,786</u>
Net loss	<u>(17,798,236)</u>	<u>(10,611,772)</u>	<u>(7,046,828)</u>	<u>(79,438,309)</u>
Deemed dividend related to beneficial conversion feature of Series B redeemable convertible preferred stock	—	—	—	<u>(3,559,305)</u>
Net loss attributable to common stockholders	<u>\$ (17,798,236)</u>	<u>\$ (10,611,772)</u>	<u>\$ (7,046,828)</u>	<u>\$ (82,997,614)</u>
Net loss per share attributable to common stockholders				
Basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.38)</u>	<u>\$ (0.64)</u>	
Weighted average shares	<u>40,179,543</u>	<u>27,831,188</u>	<u>10,936,922</u>	

(1) Includes related party transaction of \$1,075,182 cumulative from February 23, 1998 (inception) through December 31, 2006 (see note 12).

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

**Javelin Pharmaceuticals, Inc.**  
**(A Development Stage Enterprise)**  
**Statements of Redeemable Preferred Stock and**  
**Stockholders' Equity (Deficit)**

For the period from February 23, 1998 (inception) to	Series A		Series B		Series C		Additional	Unearned	Stock	Other	Deficit	Total
	Redeemable		Redeemable		Redeemable							
	Preferred Stock	Preferred Stock	Preferred Stock	Common Stock	Paid-in	Com-						
December 31, 2006, including the years ended	Shares	Amount	Shares	Amount	Shares	Amount	Capital	pen- sation	Receivable	Income	Stage	Equity
December 31, 2004, 2005 and 2006												
Sale of Common Stock to founders at inception for cash (\$0.001 per share)					4,540,812	\$ 4,541	\$ 457			(\$3,749)		\$ 1,249
Value of services provided by an affiliate (see Note 12)							89,531					89,531
Net loss for the period February 23, 1998 (inception) to December 31, 1998											(\$470,200)	(470,200)
<b>Balance at December 31, 1998</b>					<b>4,540,812</b>	<b>4,541</b>	<b>89,988</b>			<b>(3,749)</b>	<b>(470,200)</b>	<b>(379,420)</b>
Issuance of 236,128 warrants in June in connection with bridge financing (see Note 7)							101,564					101,564
Issuance of Common Stock to consultant in June for services (see Note 6)					192,985	193	93,263			(106)		93,350
Issuance of 204,336 warrants to consultants in August for services (see Note 7)							98,598					98,598
Value of services provided by an affiliate (see Note 12)							155,917					155,917
Net loss for the year ended December 31, 1999											(1,205,559)	(1,205,559)
<b>Balance at December 31, 1999</b>					<b>4,733,797</b>	<b>4,734</b>	<b>539,330</b>			<b>(3,855)</b>	<b>(1,675,759)</b>	<b>(1,135,530)</b>
Issuance of 15,522 warrants to an advisor for services in connection with sales of Series A redeemable preferred stock in August (see Note 6)							55,790					55,790
Exercise of warrants by consultants					204,336	204	(6)					198
Issuance of Common Stock in connection with acquisition of a license in September (see Note 1)					5,174,257	5,175	18,599,825					18,605,000
Sale of 160,565 Units for cash in September (\$100,000 per Unit), net of offering expenses of \$1,157,572	4,014,125	14,898,928										
Issuance of Preferred A warrants in September (see Note 6)		(960,361)					960,361					960,361
Issuance of Preferred A Finders Units for services in September (see Note 6)		(107,825)					107,825					107,825
Payment of stock subscription receivable									3,201			3,201
Non-cash compensation in connection with issuance of stock options to non-employees in August and November (see Note 10)							707,550					707,550
Value of services provided by an affiliate (see Note 12)							163,376					163,376
Net loss for the year ended December 31, 2000											(23,023,842)	(23,023,842)
<b>Balance at December 31, 2000</b>	<b>4,014,125</b>	<b>13,774,952</b>			<b>10,112,390</b>	<b>10,113</b>	<b>21,134,051</b>			<b>(654)</b>	<b>(24,699,601)</b>	<b>(3,556,091)</b>
Issuance of Series B Preferred with a beneficial conversion feature for cash in December (see Note 6)			989,991	\$ 1,935,044			3,559,305					3,559,305
Expenses in connection with sale of Series B stock				(474,317)								
Deemed dividend related to beneficial conversion feature of Series B stock (see Note 6)				3,559,305			(3,559,305)					(3,559,305)
Payment of stock subscription receivable									544			544
Exercise of warrants by a consultant					15,522	15						15
Exercise of bridge warrants					15,893	16	138					154
Value of services provided by an affiliate (see Note 12)							481,299					481,299
Net loss for the year ended December 31, 2001											(8,067,699)	(8,067,699)
<b>Balance at December 31, 2001</b>	<b>4,014,125</b>	<b>13,774,952</b>	<b>989,991</b>	<b>5,020,032</b>	<b>10,143,805</b>	<b>10,144</b>	<b>21,615,488</b>			<b>(110)</b>	<b>(32,767,300)</b>	<b>(11,141,778)</b>
Issuance of compensatory stock options to members of the Board of Directors (see Note 10)							1,431,498		(\$1,431,498)			—
Amortization of unearned compensation									1,264,522			1,264,522
Value of services provided by an affiliate (see Note 12)							185,059					185,059
Non-cash compensation in connection with issuance of stock options to a non-employee in September (see Note 10)							62,564					62,564
Reversal of subscription receivable									110			110
Net loss for the period ended December 31, 2002											(8,059,081)	(8,059,081)
<b>Balance at December 31, 2002</b>	<b>4,014,125</b>	<b>13,774,952</b>	<b>989,991</b>	<b>5,020,032</b>	<b>10,143,805</b>	<b>10,144</b>	<b>23,294,609</b>		<b>(166,976)</b>	<b>—</b>	<b>(40,826,381)</b>	<b>(17,688,604)</b>

**Javelin Pharmaceuticals, Inc.**  
**(A Development Stage Enterprise)**  
**Statements of Redeemable Preferred Stock and**  
**Stockholders' Equity (Deficit)**

For the period from February 23, 1998 (inception) to December 31, 2006, including the years ended December 31, 2004, 2005 and 2006	Series A Redeemable Preferred Stock		Series B Redeemable Preferred Stock		Series C Redeemable Preferred Stock		Common Stock		Additional Paid-in Capital	Unearned Com- pensation	Stock Sub- scription Receivable	Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Amortization of unearned compensation											113,069			113,069
Issuance of Series C Preferred as license payment in August (see Note 8)					65,360	\$ 100,000								
Conversion of Merger Note to Series C stock in August (see Note 7)					339,736	519,795								
Sale of Series C Preferred for cash in August (\$1.53 per share), net of issuance expenses of \$132,496					2,549,254	3,767,856								
Non-cash compensation in connection with issuance of stock options to a non-employee in October (see Note 10)										57,672				57,672
Exercise of bridge warrants (see Note 7)							2,270		2	20				22
Net loss for the period ended December 31, 2003													(3,155,092)	(3,155,092)
<b>Balance at December 31, 2003</b>	<b>4,014,125</b>	<b>13,774,952</b>	<b>989,991</b>	<b>5,020,032</b>	<b>2,954,350</b>	<b>4,387,651</b>	<b>10,146,075</b>	<b>10,146</b>	<b>23,352,301</b>	<b>(53,907)</b>	<b>—</b>	<b>—</b>	<b>(43,981,473)</b>	<b>(20,672,933)</b>
Conversion of Series A, B and C Preferred Stock to Common Stock (see Note 6)	(4,014,125)	(13,774,952)	(989,991)	(5,020,032)	(2,954,350)	(4,387,651)	8,187,259	8,187	23,174,448					23,182,635
Sale of common stock in a private placement (net of expense of \$1,853,224) (see Note 6)							6,139,913	6,140	16,227,307					16,233,447
Merger transaction with Intrac, Inc. (see Note 1)							1,153,190	1,153	(1,153)					—
Non-cash compensation in connection with issuance of stock options to non-employees (see Note 10)									132,501					132,501
Issuance of compensatory stock options to employees (see Note 10)									1,094,793	(1,094,793)				—
Amortization of unearned compensation										198,351				198,351
Issuance of 226,314 warrants in November in connection with Bridge Debenture financing (see Note 7)									314,795					314,795
Net loss for the period ended December 31, 2004													(7,046,828)	(7,046,828)
<b>Balance at December 31, 2004</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>25,626,437</b>	<b>25,626</b>	<b>64,294,992</b>	<b>(950,349)</b>	<b>—</b>	<b>—</b>	<b>(51,028,301)</b>	<b>12,341,968</b>
Sale of common stock in a private placement (net of expense of \$2,225,411) (see Note 6)							14,222,215	14,222	29,760,351					29,774,573
Cancellation of compensatory stock options to employees									(50,921)	50,921				—
Modification of employee stock options									125,897					125,897
Issuance of 80,184 warrants to consultants (see Note 6)									152,290					152,290
Issuance of 40,000 options to consultants (see Note 6)									95,200					95,200
Exercise of 1999 Bridge Warrants							217,964	217	1,962					2,179
Exercise of Series A Warrants							26,518	27	102,598					102,625
Issuance of stock for license payment							169,735	170	499,830					500,000
Exercise of Stock Options							1,241	1	11					12
Issuance of stock for liquidation damages							140,867	141	373,158					373,299
Amortization of unearned compensation										345,672				345,672
Net loss for the period ended December 31, 2005													(10,611,772)	(10,611,772)
<b>Balance at December 31, 2005</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>40,404,977</b>	<b>40,404</b>	<b>95,355,368</b>	<b>(553,756)</b>	<b>—</b>	<b>—</b>	<b>(61,640,073)</b>	<b>33,201,943</b>
Net loss for the period ended December 31, 2006													(17,798,236)	(17,798,236)
Unrealized loss on investments												(5,117)		(5,117)
Total comprehensive income (loss)														(17,803,353)
Exercise of 2005 private placement warrants							4,444	4	9,995					9,999
Reclassification of unearned compensation									(553,756)	553,756				—
Stock based compensation expense									2,822,939					2,822,939
<b>Balance at December 31, 2006</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>40,409,421</b>	<b>40,409</b>	<b>97,634,546</b>	<b>—</b>	<b>—</b>	<b>(5,117)</b>	<b>(79,438,309)</b>	<b>18,231,529</b>

Securities issued in connection with services or financings were valued based upon the estimate of fair value of the securities issued as determined by the Company's Management.

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

**Javelin Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Enterprise)**  
**Consolidated Statement of Cash Flows**

	Year Ended December 31,			Cumulative from February 23, 1998 (Inception) to December 31, 2006
	2006	2005	2004	
Cash flows from operating activities:				
Net loss	\$ (17,798,236)	\$ (10,611,772)	\$ (7,046,828)	\$ (79,438,309)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	61,008	44,321	31,796	178,613
Stock based compensation expense	2,822,939	—	—	2,822,939
Amortization of premium/discount on marketable securities	(36,174)	—	—	(36,174)
Amortization of deferred financing costs	—	—	25,000	252,317
Amortization of original issue discount	—	—	—	101,564
Amortization of unearned compensation	—	345,672	—	345,672
Non-cash expense recognized with issuance of Common Stock in connection with acquisition of a license	—	—	—	18,600,000
Non-cash expense recognized with issuance of Preferred Stock for license milestone	—	—	—	100,000
Non-cash expense recognized with issuance of Common Stock in connection with liquidation damages	—	373,299	—	373,299
Amortization of discount on debenture	—	—	314,795	314,795
Stock options and warrants issued in consideration for services rendered	—	373,387	330,852	3,003,076
Non-cash expense contributed by affiliate	—	—	—	1,075,182
Changes in assets and liabilities:				
(Increase) decrease in grant receivable	459,856	(458,327)	59,863	(113,645)
Increase) decrease in prepaid expenses, other current assets and other assets	41,329	(276,410)	13,799	(335,022)
(Decrease) increase in accounts payable, accrued expenses and other liabilities	1,943,756	(1,088,846)	1,306,129	3,151,382
Increase in deferred revenue	(19,522)	19,522	—	—
(Decrease) increase in deferred lease liability	47,998	(7,230)	7,075	57,869
Increase in due to Licensor	—	—	500,000	500,000
<b>Net cash used in operating activities</b>	<b>(12,477,046)</b>	<b>(11,286,384)</b>	<b>(4,457,519)</b>	<b>(49,046,442)</b>
Cash flows from investing activities:				
Purchases of short term marketable securities	(23,250,617)	—	—	(23,250,617)
Redemption of short term marketable securities	11,820,000	—	—	11,820,000
Capital expenditures	(136,306)	(68,536)	(118,629)	(415,777)
<b>Net cash (used in) provided by investing activities</b>	<b>(11,566,923)</b>	<b>(68,536)</b>	<b>(118,629)</b>	<b>(11,846,394)</b>
Cash flows from financing activities:				
Proceeds from exercise of warrants	9,999	104,804	—	115,567
Proceeds from exercise of stock options	—	12	—	12
Proceeds from sale of Common Stock	—	31,999,984	18,086,671	50,096,274
Proceeds from sale of Preferred Stock	—	—	—	25,451,201
Expenses associated with sale of Common Stock	—	(2,225,411)	(1,853,224)	(4,078,635)
Expenses associated with sale of Preferred Stock	—	—	—	(1,764,385)
Proceeds from notes payable	—	—	—	2,015,000
Proceeds from issuance of debenture	—	—	1,000,000	1,000,000
Repayment of debenture	—	—	(1,000,000)	(1,000,000)
Expenses associated with notes payable	—	—	(25,000)	(153,719)
Repayment of notes payable	—	—	—	(1,515,000)

<b>Net cash provided by financing activities</b>	<u>9,999</u>	<u>29,879,389</u>	<u>16,208,447</u>	<u>70,166,315</u>
<b>Net increase in cash and cash equivalents</b>	(24,033,970)	18,524,469	11,632,299	9,273,479
Cash and cash equivalents at beginning of period	<u>33,307,449</u>	<u>14,782,980</u>	<u>3,150,681</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>\$ 9,273,479</u>	<u>\$ 33,307,449</u>	<u>\$ 14,782,980</u>	<u>\$ 9,273,479</u>
<b>Supplemental disclosures:</b>				
Cash paid for interest:	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 16,575</u>	<u>\$ 271,633</u>
<b>Supplemental disclosure of noncash investing and financing activities:</b>				
Non cash issuance of common stock	\$ —	\$ 500,000	\$ —	\$ 500,000
Options and warrants issued for services and financings	—	—	—	\$ 1,222,574
Conversion of Merger Note and accrued interest to Series C stock	—	—	—	\$ 519,795
Recapitalization in connection with Merger with Intrac	—	—	\$ 1,153	\$ 1,153

**Javelin Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Enterprise)**  
**Notes to the Consolidated Financial Statements**

**1. Organization and Business**

Javelin Pharmaceuticals, Inc., along with its wholly owned subsidiaries Javelin Pharmaceuticals UK Limited and Innovative Drug Delivery Systems, Inc. (collectively, "we," "us," the "Company" or "Javelin"), is a development stage enterprise engaged in the research, development and commercialization of innovative treatments for the relief of moderate to severe pain. We conduct operations in a single segment in the United States of America.

In addition to the normal risks associated with a new business venture, there can be no assurance that our research and development will be successfully completed or that any approved product will be commercially viable. In addition, we operate in an environment of rapid change in technology, are dependent upon raising capital to fund operations, and are dependent upon the services of our employees, collaborators and consultants.

Javelin Pharmaceuticals, Inc. was incorporated in July 2005 in the State of Delaware by Intrac, Inc., a Nevada corporation ("Intrac"), for the purpose of migrating the Intrac corporate entity to Delaware ("the Migratory Merger"). The Migratory Merger was effective on September 7, 2005, at which time Javelin Pharmaceuticals continued the business conducted by Intrac. Through the Migratory Merger, each outstanding share of Intrac common stock was automatically exchanged for one share of Javelin Pharmaceuticals common stock. On December 6, 2004, Innovative Drug Delivery Systems, Inc. ("IDDS"), then a private operating company, consummated a merger with Intrac, a public shell company ("the Reverse Merger"). For accounting purposes, the Reverse Merger has been treated as a recapitalization of IDDS with IDDS as acquirer and with each share of IDDS common stock, stock options and warrants prior to the Reverse Merger converted to 1.018 shares of Intrac common stock, stock options and warrants following the Reverse Merger. Thus, all common share and per share data included herein have been adjusted as if the stock exchange had occurred at inception. Accordingly, IDDS is considered to have issued shares of its common stock, stock options and warrants to shareholders of Intrac in exchange for the net assets of Intrac. For the three year period prior to the Reverse Merger, Intrac's operations were nominal. The assets, liabilities and historical operating results prior to the Reverse Merger are those of IDDS. Pro forma information giving effect to the Reverse Merger has not been provided since the Reverse Merger is not considered a business combination under Statement of Financial Accounting Standards No. 141, "Business Combinations." At the time of the Reverse Merger, Intrac had 1,153,190 shares of common stock issued and outstanding, and Intrac did not hold any net assets. Therefore, since the Reverse Merger is accounted for as a recapitalization of IDDS, the Intrac common shares were included in the surviving corporation's stockholders equity at their par value with an offset to additional paid-in capital of \$1,153. As a result of the Migratory Merger, IDDS became a wholly-owned subsidiary of Javelin.

Pain Management, Inc. (the "Predecessor Company") was incorporated in the State of Delaware on February 23, 1998. On September 25, 2000, the Predecessor Company merged with IDDS. The terms of the merger provided for each share of the Predecessor Company's common stock to convert into approximately .908 shares of IDDS common stock. Accordingly, the stockholders of the Predecessor Company exchanged 5,212,500 shares of the Predecessor Company's common stock for 4,733,797 shares of IDDS common stock. Prior to the merger, IDDS had outstanding 5,174,257 shares of common stock. Following the closing of the merger, the only asset held by IDDS was a licensing agreement with West Pharmaceutical Services, Inc. (see Note 8) executed on August 25, 2000. IDDS was incorporated on April 8, 1999; however, it remained dormant until executing the merger and licensing agreements noted above. The Predecessor Company's Board of Directors and management assumed similar roles in IDDS after the merger closed. For financial reporting purposes, the merger was accounted for as the acquisition of a licensing agreement by the Predecessor Company and a reorganization with IDDS becoming the surviving entity. Consequently, the assets, liabilities and historic operating results of IDDS prior to the merger are those of the Predecessor Company. The fair value of the licensing agreement was determined to be approximately \$18.6 million based on the fair value of the common stock issued. The rights obtained under the licensing agreement related to an unproven technology that would require significant research and development effort to commercialize a product. There is also a significant uncertainty as to whether the research and development effort will be successful. Since the licensed technology has no alternative future use, the fair value of the consideration issued to obtain the licensing agreement was expensed as research and development at the time the merger closed.

**2 Summary of Significant Accounting Policies**

**Basis of Preparation**

The consolidated financial statements include the accounts of Javelin Pharmaceuticals, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

The financial statements have been prepared on a going-concern basis, which assumes realization of all assets and settlement or payment of all liabilities in the ordinary course of business. We have limited capital resources, net operating losses and negative cash flows from operations since inception and expect these conditions to continue for the foreseeable future. In addition, it is anticipated that we will not

generate significant revenues from product sales in the twelve months following December 31, 2006. Although we believe that our existing cash resources will be sufficient to support the current operating plan at least through June 30, 2007, we will need additional financing to support our operating plan thereafter or we will need to modify our operating plan accordingly. In addition, we have the ability to reduce discretionary spending to preserve cash. We may seek to raise additional funds through the private and/or public sale of our equity securities. We may also seek to raise capital through collaborative arrangements with corporate sources or other sources of financing. There can be no assurance that such additional financing, if at all available, can be obtained on terms reasonable to us. In the event that sufficient funds are not available, we will need to postpone or discontinue planned operations and projects. Our continuance as a going concern is dependent upon, among other things, our ability to obtain adequate long-term financing, the success of our research and development program and our attainment of profitable operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Use of Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relate to the valuation of equity instruments issued for services rendered, recoverability of fixed assets and deferred taxes. Actual results could differ from those estimates.

#### **Concentrations of Credit Risk**

Financial instruments which potentially subject us to concentrations of credit risk consist of cash, cash equivalents, marketable securities and receivables from the U.S. Department of Defense ("DOD"). We have established investment guidelines that relate to credit quality and diversification and that limit exposure to any one issue of securities.

#### **Cash and Cash Equivalents**

We consider all highly liquid investments which have maturities of three months or less, when acquired, to be cash equivalents. Our cash and cash equivalents are comprised of demand deposit accounts, money market accounts and U.S. Treasury obligations. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

#### **Marketable Securities**

Short-term marketable securities consist of certificates of deposit, government securities and corporate auction-rate securities with original maturities of greater than three months at the time of purchase. As of December 31, 2006, all the auction-rate securities held have original maturities in excess of 1 year. Our investment policy permits investments in auction-rate securities that have interest reset dates of three months or less at the time of purchase. The reset date is the date on which the underlying interest rate is revised based on a Dutch auction and the underlying security may be readily sold. Although the securities held have extended maturities, we classify these securities as current as they are available for sale under SFAS No. 115 — Accounting for Certain Investments in Debt and Equity Securities. All available-for-sale securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive loss in shareholders' equity. Realized gains and losses and declines in value, if any, judged to be other-than-temporary on available-for-sale securities are reported in other expense. The cost of available-for-sale securities sold is based on the specific identification method. We have established guidelines that maintain safety and provide adequate liquidity in our available-for-sale portfolio. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. We have not recognized any charges for unrealized losses on available-for-sale securities that were determined to be other-than-temporary.

#### **Fixed Assets**

Furniture and fixtures, laboratory equipment, and computer equipment and software are stated at cost and are depreciated on a straight-line basis over their estimated useful lives. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation of assets retired or sold are removed from the respective accounts and any gain or loss is recognized in operations.

The estimated useful lives of fixed assets are as follows:

Leaseholds	3 years
Laboratory equipment	7 years
Furniture and fixtures	5 years
Computer equipment and software	3 years

## Revenue Recognition

We have been awarded government grants and contracts from the DOD and the National Institutes of Health (the "NIH"), which are used to subsidize our research and development projects ("Projects"). This revenue is recognized as subsidized Project costs for each period are incurred. For the year ended December 31, 2002, our revenue included \$214,856 and \$72,390 from the DOD and the NIH, respectively. In May 2003, we were granted an extension of a prior grant by DOD in the amount of a \$4.3 million contract. For the years ended December 31, 2006, 2005 and 2004, all of our research revenue came from reimbursements for costs incurred in relation to the contract from the DOD. For all periods presented, our only source of revenue was in the form of grants and contracts.

Interest income is recognized as earned.

## Research and Development Costs

We expense all research and development costs as incurred for which there is no alternative future use. Such expenses include licensing and upfront fees paid in connection with collaborative agreements, as well as expenses incurred in performing research and development activities including salaries and benefits, clinical trial and related clinical manufacturing expenses, share-based compensation expense, contract services and other outside expenses. For the years ended December 31, 2006, 2005 and 2004, we received reimbursements for research and development costs incurred in relation to the contract from the DOD, described above. For the years ended December 31, 2006, 2005 and 2004, research and development expenses that were incurred and reimbursed under our DOD grants and contracts were \$842,171, \$1,547,753, and \$836,841, respectively.

## Patents

As a result of research and development efforts conducted by us, we have applied, or are applying, for a number of patents to protect proprietary inventions. All costs associated with patents are expensed as incurred.

## Net Loss Per Share

We prepare our per share data in accordance with Statement of Financial Accounting Standards No. 128, "Earnings Per Share" ("SFAS No. 128"). Basic net loss per share is computed on the basis of net loss for the period divided by the weighted average number of shares of common stock outstanding during the period. Since we have incurred net losses since inception, diluted net loss per share does not include the number of shares issuable upon exercise of outstanding options and warrants and the conversion of preferred stock since such inclusion would be anti-dilutive.

Disclosures required by SFAS No. 128 have been included in Note 9.

## Deferred Financing Costs

Costs incurred in connection with issuance of notes payable are deferred and amortized using the interest method as interest expense over the term of the debt instrument.

## Comprehensive Loss

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income", established standards for reporting and display of comprehensive loss and its components in the financial statements. For the year ended December 31, 2006, our comprehensive loss was \$17.8 million, which consisted of our net loss and \$5,117 of unrealized loss on marketable securities. We had no other comprehensive items to report other than net loss for the years ended December 31, 2005 and 2004, respectively.

## Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", we review our long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. An impairment loss is recognized if the carrying amount of the long-lived asset is not recoverable and its carrying amount exceeds its fair value, which is based upon estimated undiscounted future cash flows. For all periods presented, there have been no impairment losses incurred.

## Stock-Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004) — Share-Based Payment, or SFAS 123(R). This Statement requires compensation cost relating to share-based payment transactions to be recognized in the financial statements using a fair-value measurement method. Under the fair value method, the estimated fair value of an award is charged against

income on a straight-line basis over the requisite service period, which is generally the vesting period. We selected the modified prospective adoption method as prescribed in SFAS 123(R) and therefore, we have not restated our financial statements for prior periods. Under the modified prospective application, this Statement was applied to new awards granted in 2006, as well as to the unvested portion of previously granted stock option awards for which the requisite service had not been rendered as of January 1, 2006.

Prior to January 1, 2006, our stock option plan was accounted for under the recognition and measurement provisions of APB Opinion No. 25 Accounting for Stock Issued to Employees, and related interpretations, as permitted by Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation. Generally, no compensation expense was recognized in the financial statements in connection with the awarding of stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the fair value of our stock, as of the grant date, is equal to or less than the amount an employee must pay to acquire the stock. We had recognized compensation expense in situations where the terms of an option grant were not fixed or where the fair value of our common stock on the grant date was greater than the amount an employee must pay to acquire the stock.

The adoption of SFAS 123(R) had and will have a material impact on our consolidated financial position and results of operations. See Note 10 for further information regarding our stock-based compensation assumptions and expenses, including pro forma disclosures for prior periods as if we had recorded stock-based compensation expense.

### Income Taxes

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

### Recent Accounting Pronouncements

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements" (SAB 108), which provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. We have adopted the provisions of SAB 108 in our annual financial statements for fiscal year 2006. The adoption of SAB 108 did not have a material impact on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this Statement relate to the definition of fair value, the methods used to measure fair value, and the expanded disclosures about fair value measurements. We will be required to adopt the provisions of SFAS 157 beginning with our first quarter ending March 31, 2007. We do not believe that the adoption of the provisions of SFAS 157 will materially impact our consolidated financial statements.

In July 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires an entity to recognize the impact of a tax position in its financial statements if that position is more likely than not to be sustained on audit based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of fiscal year 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. Early application of FIN 48 is encouraged. We do not expect that our adoption of FIN 48 will materially impact our consolidated financial statements.

### 3. Marketable Securities

The following is a summary of our short term marketable securities available for sale as of December 31, 2006:

	Carrying Value	Unrealized Gains	Unrealized Losses	Estimated Fair Value
December 31, 2006:				
Short-term marketable securities:				
Certificates of Deposit	\$ 1,698,006	\$ 713	\$ (137)	\$ 1,698,582
U.S. Government Securities	2,398,785	—	(5,693)	2,393,092
Taxable Auction Securities	7,370,000	—	—	7,370,000
Total short term marketable securities	<u>\$ 11,466,791</u>	<u>\$ 713</u>	<u>\$ (5,830)</u>	<u>\$ 11,461,674</u>

In accordance with FASB Staff Position FAS115-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," the following table summarizes the fair value and gross unrealized losses related to available-for-sale securities, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2006:

	Less than 12 months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
December 31, 2006:						
Certificates of Deposit	\$ 496,800	\$ (137)	\$ —	\$ —	\$ 496,800	\$ (137)
U.S. Government Securities	2,393,092	(5,693)	—	—	2,393,092	(5,693)
<b>Total</b>	<b>\$ 2,889,892</b>	<b>\$ (5,830)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 2,889,892</b>	<b>\$ (5,830)</b>

We have the intent and ability to hold these securities with unrealized losses to maturity or to recovery. Based on both the length of time and the extent to which the market value has been less than cost and the financial condition and near-term prospects of the issuer, we concluded that none of the unrealized losses at December 31, 2006 constituted other-than-temporary impairment.

#### 4. Fixed Assets

Fixed assets consist of the following:

	December 31,	
	2006	2005
Leaseholds	\$ 15,435	\$ 4,824
Furniture and fixtures	113,474	60,800
Laboratory equipment	114,593	116,901
Computer equipment	136,204	76,175
Computer software	33,764	20,771
	413,470	279,471
Less, Accumulated depreciation	(176,307)	(117,605)
	<b>\$ 237,163</b>	<b>\$ 161,866</b>

Depreciation expense was \$61,008, \$44,321 and \$31,796 for 2006, 2005 and 2004, respectively.

#### 5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31,	
	2006	2005
Accounts payable	\$ 685,400	\$ 557,252
Accrued professional fees	220,333	434,886
Accrued research and development	964,944	56,897
Accrued compensation and benefits	878,808	133,044
Accrued sales and marketing consulting costs	325,165	—
Accrued other expenses	76,729	25,547
	<b>\$ 3,151,379</b>	<b>\$ 1,207,626</b>

#### 6. Stockholders' Equity

At December 31, 2006, our Certificate of Incorporation, as amended by shareholder approval on July 20, 2006, authorizes us to issue 200 million shares of our common stock, \$0.001 par value, and 5 million shares of our preferred stock, \$0.001 par value. At December 31, 2005, our Certificate of Incorporation authorized us to issue 100 million shares of our common stock, and 5 million shares of our preferred stock. At December 31, 2004, our Certificate of Incorporation, as amended, authorized us to issue 500 million shares of our common stock and 5 million shares of our preferred stock. Our Board of Directors has the authority to issue our preferred stock, in series, with rights and privileges determined by the Board.

Prior to the Reverse Merger, IDDS was authorized to issue 80 million shares of common stock, \$0.001 par value, and 20 million shares of preferred stock, \$0.001 par value. At that time, IDDS had outstanding three classes of redeemable preferred stock. The rights and provisions of the preferred stockholders included liquidation, voting, dividend, redemption and conversion. As a result of the Reverse Merger, all shares of IDDS preferred stock converted into 8,187,259 shares of common stock.

In 1999, we issued 192,985 shares of common stock to a consultant in consideration for services rendered and a subscription receivable of \$106. The fair value of the shares was \$93,456, as estimated by us.

In September 2000, we sold 160,565 units ("Units" or "Series A Financing") to investors at a per Unit price of \$100,000. Each Unit consisted of 25,000 shares of Series A redeemable Preferred Stock ("Series A Stock") (convertible into 25,872 shares of common stock) and 2,587 warrants (the "A Preferred Warrants"). Each A Preferred Warrant entitles the holder to purchase one share of Common Stock at an exercise price of \$3.87 per share. The A Preferred Warrants contain certain antidilution provisions, as defined. The fair value of the A Preferred Warrants at issuance was \$960,361. On October 13, 2005, 388,885 A Preferred Warrants expired unexercised. At December 31, 2005, 26,518 of the A Preferred Warrants had been exercised (see Note 11).

As partial consideration for the sale of the Units, we issued an option to purchase 15.83 units (the "Finders Units") to members of the firm responsible for obtaining the Series A Financing. Each Finders Unit entitles the holder to purchase 25,000 shares of Series A Stock (convertible into 25,872 shares of Common Stock) and 2,587 Series A Preferred Warrants (the "Finders Warrants") for \$110,000 per Finders Unit. The fair value of the Series A Stock included in the Finders Units, which was accounted for as a cost of the Series A Financing, totaled \$1,071,331. Each Finders Warrant entitles the holder to purchase one share of Common Stock at a per share price of \$3.87. The Finders Warrants expire in September 2007. The fair value of the Finders Warrants at the date of issue was \$107,825. At December 31, 2006, none of the Finders Warrants had been exercised.

In 2000, we issued to another consultant, who acted as an advisor to the Series A Financing, warrants to purchase up to 15,522 shares of common stock at an exercise price of approximately \$0.001 per share. The fair value of the warrants at the issuance date was \$55,790, which has been accounted for as a cost of the Series A Financing. All of the warrants were exercised in 2001.

During December 2001, we issued shares of Series B Redeemable Preferred Stock ("Series B Stock"). The Series B conversion price represented a discount from the estimated fair value of the Common Stock at the time of issuance. Accordingly, the discount amount was considered incremental yield ("the beneficial conversion feature") to the preferred stockholders and has been accounted for as a deemed dividend to preferred stockholders. Based on the conversion terms of the Series B Stock, a deemed dividend of approximately \$3.6 million has been added to the net loss in the calculation of net loss applicable to common stockholders in the year ended December 31, 2001.

In December 2004 we closed the private placement of 6,139,913 shares of common stock for proceeds of approximately \$16.2 million, net of offering expenses of \$1.9 million. As partial consideration for services rendered, we issued to the placement agent fully vested warrants, to purchase up to 920,987 shares of common stock (the "Placement Warrants"). Each Placement Warrant entitles the holder to purchase one share of common stock at an exercise price of \$2.95 per share. The Placement Warrants expire in December 2009. The fair value of the Placement Warrants at issuance was approximately \$1.8 million, as estimated by us, using the method described in Note 10.

In March 2005, in consideration of a termination fee, we granted warrants to an entity to purchase up to 10,184 shares of common stock at an exercise price of \$2.49 per share. The warrants expire in March 2010. The fair value of the warrants at the date of issuance was \$18,840, as estimated by us using the method described in Note 10.

Also in March 2005, as part of an engagement fee for investor and public relations services, we granted warrants to an entity to purchase up to 25,000 shares of common stock at an exercise price of \$3.00 per share. The warrants expire in March 2010. The fair value of the warrants at the date of issuance was \$44,000, as estimated by us using the method described in Note 10.

In April 2005, in consideration for investor and public relations services, we granted warrants to an entity to purchase up to 20,000 shares of common stock at an exercise price of \$3.00 per share. The warrants expire in April 2010. The fair value of the warrants at the date of issuance was \$35,200, as estimated by us using the method described in Note 10.

In September 2005, as partial consideration for investor and public relation services, we granted warrants to an entity to purchase up to 25,000 shares of common stock at an exercise price of \$3.00 per share. The warrants expire in September 2010. The fair value of the warrants at the date of issuance was \$54,250, as estimated by us using the method described in Note 10.

In November 2005 we closed the private placement of 14,222,215 shares of common stock and 711,111 warrants (the "Investor Warrants") for proceeds of approximately \$29.8 million, net of offering expenses of \$2.2 million. Each Investor Warrant entitles the holder to purchase one share of common stock at an exercise price of \$2.25 per share. The Investor Warrants expire in December 2010 and contain certain antidilution provisions and registration rights, as defined. The fair value of the Investor Warrants at issuance was \$1,376,000, as estimated by us, using the method described in Note 10. As partial consideration for services rendered, we issued to the placement agents fully vested warrants to purchase up to 853,333 shares of common stock (the "Placement Warrants"). Each Placement Warrant entitles the holder to purchase one share of common stock at an exercise price of \$2.48 per share. The Placement Warrants expire in November 2010. The fair value of the Placement Warrants at issuance was approximately \$1.6 million, as estimated by us, using the method described in Note 10.

## 7. Notes Payable

- a. During 1998, we issued two notes payable to two banks with principal amounts of \$145,000 and \$80,000, respectively (the "Notes"). The Notes were due in September 2000 bearing interest of 1% over the Eurodollar rate and the bank's prime rate, respectively. The Notes were guaranteed by one of our investors. At December 31, 1999, the outstanding balances on the Notes were \$145,000 and \$80,000, respectively, accrued interest totaled \$1,400 and the weighted average interest rate was 7.5%. During 2000, the \$145,000 Note was increased to \$245,000.

Both Notes were repaid in October 2000, following the issuance of Series A Stock (see Note 6).

- b. During 1999, we raised \$1.04 million by issuing notes payable (the "Bridge Notes") and warrants (the "Bridge Warrants"). The Bridge Notes accrued interest at 12% per annum for the first twelve months and 15% per annum for up to an additional year. At December 31, 1999, accrued interest on the Bridge Notes was approximately \$86,000. In November, 2000, after the issuance of Series A Stock, the principal plus accrued interest totaling approximately \$1,238,000 was repaid.

In connection with the Bridge Notes, Bridge Warrants to purchase up to 236,127 shares of Common Stock, with an exercise price of approximately \$0.01 per share, were issued to the Bridge Noteholders. The Bridge Warrants contain anti-dilution provisions and were to expire in September 2005. The fair value of the Bridge Warrants at the date of issue was \$101,564. Accordingly, the Bridge Notes were recorded at an original issue discount of \$101,564, which was amortized to interest expense over the term of the Bridge Notes. At December 31, 1999, the Bridge Notes were recorded at \$980,256. During the years ended December 31, 2001, 2003 and 2005, Bridge Warrants to purchase 15,893 shares, 2,270 shares and 217,964 shares of common stock, respectively, were exercised. At December 31, 2005, all Bridge Warrants had been exercised (see Note 11).

Professional fees incurred in connection with the issuance of the Bridge Notes, amounting to \$128,719, were accounted for as deferred financing costs.

In 1999, we issued to three consultants who had arranged the sale of Bridge Notes warrants to purchase up to 204,336 shares of common stock at an exercise price of approximately \$0.001 per share. The fair value of the warrants, which were accounted for as deferred financing costs, at the issuance date was \$98,598. All of the warrants were exercised in 2000.

- c. In July 2000, we issued a one-year note to a commercial bank in the principal amount of \$150,000 and bearing interest, payable monthly, based on the Eurodollar rate plus 1%. The note was guaranteed by one of our investors. In October 2000, following the closing of the sale of Series A Stock, the note was repaid.
- d. In November 2002, we issued a \$500,000 convertible note, due on November 24, 2004, to eXegenics, Inc., pursuant to an agreement for the termination of a proposed merger with eXegenics, Inc. (the "Merger Note"). The Merger Note was bearing interest at prime plus 1%, as defined, which interest was due and payable annually. The unpaid principal and accrued interest on the Merger Note was to automatically convert into shares of our equity securities in the event that we completed a private placement, as defined, before November 24, 2004, or in the event of a consolidation, merger, combination, or reorganization, as defined. In the event of a private placement, the Merger Note and accrued interest was to be converted into the same series of securities offered in the private placement, at the same per share price paid by investors. At December 31, 2002, accrued interest on the Merger Note totaled \$2,625. In August 2003, following a private placement, the principal and accrued interest, totaling \$519,795, was converted into 339,736 shares of Series C Redeemable Preferred Stock (see Note 6).
- e. In November 2004, we entered into a Securities Purchase Agreement and raised \$1.0 million by issuing a Senior Secured Debenture (the "Bridge Debentures") and warrants (the "Warrants"). The Bridge Debentures accrued interest at 10% per annum for a maximum term of 12 months. Subject to certain terms and conditions we granted to investors in the Bridge Debenture a security interest in certain of our assets. At December 6, 2004, upon the sale of common stock (see Note 6), the principal plus accrued interest totaling \$1,008,611 was repaid, and the security interest in our assets was released.

In connection with the issuance of the Bridge Debentures, we issued warrants to purchase up to 226,314 shares of common stock, with an exercise price of \$2.65 per share to the purchasers of the Bridge Debentures. The warrants contain anti-dilution provisions and expire in November 2009. We allocated the total proceeds to the fair value of the Bridge Debentures and the Warrants in accordance with APB No. 14, which resulted in \$314,795 being allocated to the warrants. This amount was accounted for as debt discount and amortized to interest expense over the term of the Bridge Debentures. Professional fees incurred in connection with the Bridge Debentures, amounting to \$25,000, were accounted for as deferred financing costs and amortized as additional interest expense during the year ended December 31, 2004.

## 8. Commitments and Contingencies

### a. Operating Leases

We recognize rental expense for leases on the straight-line basis over the life of the lease.

On September 5, 2002, we entered into a sublease (the "Sublease") for office space in New York, New York with a term from December 7, 2002 through December 30, 2003. Minimum rent for the Sublease was \$371,000 per annum, payable in equal monthly installments of \$30,917, except that no rent payment was due for the first 30 days of the Sublease term (the "Free Rent Period"). In addition, upon execution of the Sublease, we prepaid rent for the first two months following the Free Rent Period and the last two months of the Sublease term, totaling \$123,667. We also were required to pay additional rent, as defined. On September 22, 2003, we entered into a lease for office space in New York, New York with a term from December 1, 2003 through November 30, 2006. Minimum rent for the lease was initially \$125,000 per annum with a 3% rent escalation every 12 months thereafter, payable in equal monthly installments, except that no rent payment was due for the first 60 days of the lease term (the "Free Rent Period"). In addition, upon execution of the lease, we paid a security deposit of \$31,250. We vacated the New York office space upon termination of the lease, and received the remainder of our security deposit in January 2007.

On May 1, 2005, we entered into a lease for office space in Cambridge, Massachusetts, which lease was amended effective June 1, 2006. Prior to the amendment, minimum rent for the lease was payable in equal monthly installments of \$6,810 over the lease term. As a result of the amendment, we assumed additional office space in our Cambridge facility, the lease term was extended to May 31, 2012, and the minimum monthly rent for the lease was increased to \$15,450 for the first twelve months, with rent escalations every twelve months thereafter. At December 31, 2006, our security deposit related to the lease was \$97,615.

In August 2006, we entered into a new lease for office space in Lake Success, New York with a three-year extendable term, which commenced on October 1, 2006. Minimum rent for the lease is initially \$57,477 per annum, with an annual 3.5% rent escalation. In addition, upon execution of the lease, we paid a security deposit of \$9,580.

For the years ended December 31, 2006, 2005 and 2004, we recognized rent expense of \$326,301, \$176,771 and \$122,355, respectively. A deferred lease liability of \$57,869, \$9,871 and \$17,101 at December 31, 2006, 2005 and 2004, respectively, was recorded for rent expense in excess of amounts paid; the amount of additional rent paid was immaterial.

In December 2006, we entered into a three month extendable term lease for office space in the United Kingdom for Javelin Pharmaceuticals UK Ltd., effective January 1, 2007. Minimum rent is approximately \$1,000 per month. We also paid a security deposit of approximately \$2,000.

Future minimum lease payments under operating leases having initial or remaining noncancellable lease terms in excess of one year are as follows:

	As of December 31, 2006
2007	\$ 294,988
2008	340,245
2009	336,667
2010	306,320
2011	320,108
Thereafter	135,210
	<u>\$ 1,733,538</u>

### b. Legal Proceedings

From time to time, we are involved in disputes or legal proceedings arising in the ordinary course of business. However, we do not believe that any such disputes or pending litigation would have a material adverse effect on our financial position, results of operations or cash flows.

### c. Research Collaboration, Licensing and Consulting Agreements

- (i) In September 2000, we assumed a license agreement, dated February 25, 1998, between the Predecessor Company and Stuart Weg, M.D. The license granted us exclusive worldwide rights, including the right to grant sublicenses, for the intellectual property surrounding transnasal ketamine. In connection therewith, we made an upfront payment to Dr. Weg, Herbert Brotspies, and Calgar & Associates (collectively the "Founders") and issued the Founders shares of common stock, of which a portion is held in escrow and will be released to the Founders, if at all, upon the successful completion of the Phase III trial.

The release of the shares from escrow is not contingent on the Founders' performance. We also reimbursed the Founders for patent and other costs. We will pay semi-annual royalty payments to the Founders based on a percentage of net sales of transnasal ketamine by us or our sublicensees.

In addition, we shall pay the Founders a defined percentage of all sublicensing fees or other lump sum payments. Under the terms of the license agreement, we are also obligated to make aggregate future payments upon the earlier of certain defined dates or satisfaction of certain clinical and regulatory milestones, which include the filing of a New Drug Application ("NDA") with the Food & Drug Administration ("FDA"), the approval of an NDA by the FDA and the first commercial sale of a licensed product. A defined percentage of such milestone payments shall be creditable against royalties earned; provided, however, that in no event shall royalties earned be reduced by more than a certain percentage in any applicable semi-annual period. We may satisfy a portion of the milestone payments through the issuance of shares of our common stock provided that we are publicly traded at the time such milestone payment accrues. In April 2003 the license agreement was amended to allow for the August 2003 milestone to be paid in cash and Series C Stock. The Founders agreed to accept 65,360 shares of Series C Stock, valued at \$0.1 million plus \$0.15 million in cash as payment in full for the milestone. In November 2004, the license agreement was amended to defer payment of the \$500,000 milestone from August 25, 2004, to a date on or before December 31, 2004. We were required to pay interest, at a rate of 4.75% per annum, on the amount of the milestone payment for the period from August 25, 2004 to the amended payment date. On December 21, 2004 we paid the milestone payment plus accrued interest totaling \$507,964. On December 31, 2004 we accrued the final milestone payment of \$500,000 and on April 7, 2005, we entered into an agreement and issued 169,735 shares of common stock as settlement of this final milestone payment, under the license agreement. The fair value of the shares issued was \$500,000, as determined by the equity price of \$2.95 on the date of grant.

- (ii) In connection with the license agreement described above, in February 1998 the Predecessor Company entered into a three year Consulting Agreement, renewable upon mutual consent, with each of Dr. Weg and Dr. Gary, pursuant to which both Dr. Weg and Dr. Gary were to provide us with such consulting services as we may reasonably request. In consideration for such services, we agreed to pay to each of Dr. Weg and Dr. Gary a consulting fee equal to \$75,000 per year, payable in equal monthly installments. These agreements expired March 2001 and were not renewed.
- (iii) On August 25, 2000, we entered into a license agreement with West Pharmaceutical Services, Inc. ("West") for rights to develop and commercialize intranasal morphine, fentanyl and other products. Under the terms of the agreement, we were granted an exclusive, worldwide, royalty bearing license, including the right to grant sublicenses, for the rights to the intellectual property covering these products. The license agreement will expire with the last to expire of the license patents in 2016. In consideration of the license, we paid and expensed on September 22, 2000 an up front fee. In addition, we are obligated to make royalty payments to West based upon net sales of products by us or our sublicensees, if any, as defined. We are also obligated to pay West a minimum annual royalty for each licensed product that receives approval by a regulatory agency to be marketed in any major market country, as defined, and to pay West a defined amount of any up-front license fees in the event that we sublicense any rights to any third party. In addition, under a Development Milestone and Option Agreement entered into in connection with the license agreement, we are obligated to make aggregate future payments totaling \$5.0 million upon reaching certain defined development milestones, including the filing of an NDA with the FDA and the approval of an NDA by the FDA of a licensed product. Milestone payments can be paid in cash or equity upon the satisfaction of certain clinical and regulatory milestones and provided that we are publicly traded at the time such milestone payment accrues. Our ability to pay the upfront payment for the license agreement and the M-6-G fee (see below) was guaranteed by an affiliate of ours. The guarantee expired upon the payments by us of amounts owed to West. In addition, we granted West the right of first refusal to enter into a clinical manufacturing agreement for nasal morphine (see (iv) (a) below).

The license agreement and related agreements (see (iv)(a) to (iv)(d) below) may be terminated by mutual consent of the parties at any time or by either party upon written notice of default, including non-performance, by the other party that is not cured within 30 days.

- (iv) In connection with the West license agreement, we entered into the following additional agreements:
  - (a) A clinical manufacturing agreement, whereby we would buy from West 100% of the nasal morphine product required for conducting the clinical trials subject to West's ability to supply 100% of the required product. West would manufacture and package the clinical product for us. This agreement was terminated effective September 2002.
  - (b) An option agreement, whereby we were granted an option to include morphine -6- glucuronide ("M-6-G") as an identified compound under the license agreement. We paid and expensed a non-refundable fee in consideration of the option, which expired unexercised on December 22, 2000.
  - (c) On October 24, 2000, we expanded our license agreement to include an additional development agreement with West for rights to develop and commercialize intranasal fentanyl. Pursuant to the development agreement, we would undertake a development program for intranasal fentanyl with West, and the parties would endeavor to complete the development program

within the defined time table. However, we could use other suppliers should West be unable to either provide competitive cost bids or complete the program within a reasonable timeframe. In addition, under the development agreement, we were obligated to make aggregate future payments totaling \$6.3 million upon reaching certain defined development milestones, which included completion of proof-of-principle studies, successful completion of a phase I/II clinical trial, commencement of a phase III clinical trial, filing of an NDA with the FDA and the approval of an NDA by the FDA of a licensed product. These milestone payments could be paid in cash or equity upon the satisfaction of certain clinical and regulatory milestones and provided that we were publicly traded at the time such milestone payment accrues. In October 2003, we and West amended the license agreement to exclude further development of fentanyl by us. All rights, duties and obligations between us and West related to fentanyl were terminated, including aggregate remaining future milestone payments of \$6.3 million.

- (d) On November 17, 2000, we entered into a clinical manufacturing agreement with West to manufacture, package, purchase and sell to us nasal ketamine clinical product according to agreed upon clinical product specifications and price schedule. The agreement expired in November 2001.
- (v) On February 8, 2005, we consented to the assignment of the license agreements with West to Archimedes Pharma Limited (“Archimedes”) in connection with the sale of West’s Drug Delivery business to Archimedes. Under the terms of the assignment, Archimedes assumed all of West’s obligations and liabilities under the assigned agreements that by their respective terms are required to be paid, performed or discharged.
- (vi) On December 14, 2001 (the “Effective Date”), we entered into an agreement (the “Shimoda Agreement”) with Shimoda Biotech (Proprietary) Ltd. and certain affiliated entities (“Shimoda”), for an exclusive worldwide license to commercialize formulations of pharmaceutical products containing diclofenac. We would pay: (i) a license fee to Shimoda and reimbursement for expenses, if certain defined events occur; (ii) two percent of the net proceeds, as defined, of our initial public offering (“IPO”) to Shimoda, but not less than \$1 million or in excess of \$2 million; (iii) aggregate future milestone payments of \$6.0 million payable upon the satisfaction of certain clinical and regulatory milestones which includes submission of an NDA with the FDA, approval of an NDA by the FDA and one year following the date of first sale of a licensed product; and (iv) royalty payments to Shimoda based upon the sales of products by us or our sublicensees, if any, as defined. Upon achievement of a milestone, Shimoda has the option to receive payment in cash or shares of common stock. In the event Shimoda elects to receive common stock, the number of shares to be issued is based on a formula whereby the defined milestone payment is divided by the per share price of our common stock in an IPO as defined. Should common stock be issued in satisfaction of milestones, we will record a non-cash charge based on the fair value of the consideration paid at the date the milestone is achieved. Such charge could be material and could result in a material dilution to per share amounts. The Shimoda Agreement may be terminated (i) by either party due to breach by the other party that is not cured within 60 days of written notice; (ii) by Shimoda in the event of default by us for non-payment of amounts due that is not cured with 60 days of written notice; or (iii) by us at any time by giving 90 days written notice to Shimoda.
- (vii) In December 2005, we amended the license agreement with Shimoda. Under the terms of the amendment, the total aggregate future milestone payments of \$6.0 million payable upon the satisfaction of certain clinical and regulatory milestones remains unchanged although as amended include allowance of an MAA by the MHRA, submission of an NDA with the FDA, approval of an NDA by the FDA and one year following the date of first sale of a licensed product.
- (viii) In May 2006, we further amended the license agreement with Shimoda. Under the previous agreement, we were required to launch a commercial product by December 14, 2007 or risk termination of the license at Shimoda’s option. Under the terms of the amendment, we are no longer required to launch a commercial product by December 14, 2007. Rather, we will be considered to be compliant with the Agreement if we diligently continue to pursue regulatory approval as of that date.
- (ix) In February 2007, we entered into a Commercial Supply Agreement (the “Supply Agreement”) with Precision Pharma Services, Inc. (“Precision”). The initial term of the Supply Agreement is two years, and it is renewable in one-year increments. Under the Supply Agreement, Precision agreed to manufacture our requirements for the supply of Dyloject™, in accordance with U.S. and E.U. good manufacturing practices. We committed to purchase at least \$7,650,000 worth of product during the two year period beginning on April 1, 2007. Either party may terminate the Supply Agreement upon written notice if the other party is in material breach of any provision thereof, subject to applicable thirty (30) or ninety (90) day cure periods. Either party may also terminate the Supply Agreement upon sixty (60) days’ prior written notice upon the occurrence of certain events involving the bankruptcy or insolvency of the other party, and the Supply Agreement shall automatically terminate upon the occurrence of certain events specified therein. Moreover, we may elect to terminate the Supply Agreement if Precision fails to meet its performance obligations regarding the manufacture of Dyloject™ in accordance with good manufacturing practices, and under certain other conditions.

## 9. Net Loss per Share

Our basic net loss per share amounts have been computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For all periods presented, we reported a net loss and, therefore, common stock equivalents were not included since such inclusion would have been anti-dilutive. In addition, for all periods presented, 227,044 shares of Common Stock were held in escrow. These shares have been excluded from the calculation of basic and diluted per share amounts.

The calculation of net loss per share, basic and diluted, for the periods ending December 31 is as follows:

	2006	2005	2004
Numerator:			
Net loss, basic and diluted	\$ (17,798,236)	\$ (10,611,772)	\$ (7,046,828)
Denominator:			
Weighted average common shares	40,179,543	27,831,188	10,936,922
Net loss per share, basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.38)</u>	<u>\$ (0.64)</u>

Common stock equivalents and shares issuable upon conversion of redeemable convertible preferred stock which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following:

	2006		For the Years Ended December 31, 2005		2004	
	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price	Weighted Average Number	Weighted Average Exercise Price
Options	6,120,904	\$ 2.99	4,889,467	\$ 2.91	3,730,257	\$ 3.06
Warrants	2,830,051	2.62	1,922,888	2.81	770,226	2.65
Convertible Preferred Stock	—		—		7,648,919	
Total	<u>8,950,955</u>		<u>6,812,355</u>		<u>12,149,402</u>	

## 10. Share Based Compensation Adoption of SFAS 123(R)

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004) — Share-Based Payment, or SFAS 123(R). This Statement requires compensation cost relating to share-based payment transactions to be recognized in the financial statements using a fair-value measurement method. Under the fair value method, the estimated fair value of an award is charged against income on a straight-line basis over the requisite service period, which is generally the vesting period. We selected the modified prospective adoption method as prescribed in SFAS 123(R) and therefore, we have not restated our financial statements for prior periods. Under the modified prospective application, this Statement was applied to new awards granted in 2006, as well as to the unvested portion of previously granted stock option awards for which the requisite service had not been rendered as of January 1, 2006.

Prior to January 1, 2006, our stock option plan was accounted for under the recognition and measurement provisions of APB Opinion No. 25 Accounting for Stock Issued to Employees, and related interpretations, as permitted by Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation. Generally, no compensation expense was recognized in the financial statements in connection with the awarding of stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the fair value of our stock, as of the grant date, is equal to or less than the amount an employee must pay to acquire the stock. We had recognized compensation expense in situations where the terms of an option grant were not fixed or where the fair value of our common stock on the grant date was greater than the amount an employee must pay to acquire the stock.

As a result of the adoption of SFAS 123(R), we recorded share-based compensation for 2006 as follows:

	2006
Research and development	\$ 924,218
Selling, general and administrative	1,898,721
Total impact on results of operations	<u>\$ 2,822,939</u>
Per share impact on results of operations	<u>\$ 0.07</u>

We have not capitalized any compensation cost. We recorded stock based compensation charges of \$479,442, related to the extension of the term to exercise certain stock option grants to two employees who terminated employment and a Board member who resigned in 2006 and acceleration of vesting of stock options for two members of the Board of Directors who resigned from the Board during 2006. No options were exercised during 2006 and no cash was used to settle equity instruments granted under our stock option plans. At January 1, 2006, there was no cumulative pre-tax adjustment resulting from the compensation cost recorded prior to the adoption of SFAS123(R) under APB 25.

The fair value of the stock option grants were estimated on the date of grant using the Black-Scholes option valuation model that uses the following assumptions:

	<u>2006</u>
Expected volatility	80%
Expected life	5.0 years
Dividend yield	0%
Risk free interest rate	4.5% - 5.2%
Weighted average per share grant date fair value	\$2.50

Expected volatility is based upon implied volatility for our common stock and other factors. The expected term of stock options granted is derived from using the assumed exercise rates based on historical exercise patterns, and represents the period of time that options granted are expected to be outstanding. The risk free interest rate used is based upon the published U.S. Treasury yield curve in effect at the time of grant for instruments with a similar life. The dividend yield is based upon the fact that we have not historically granted dividends, and do not expect to in the future. Stock options granted prior to January 1, 2006 were valued based on the grant date fair value of those awards, using the Black-Scholes option pricing model, as previously calculated for pro-forma disclosures under SFAS 123 — Accounting for Stock-based Compensation.

## Stock Incentive Plans

### *Omnibus Plans*

In February 2001, the Board of Directors and stockholders of IDDS approved the adoption of the 2000 Omnibus Stock Incentive Plan (the "IDDS Plan"). The IDDS Plan, as amended, provided for the issuance of 4,200,000 shares of IDDS common stock to be awarded to employees, consultants, directors and other individuals who render services to IDDS (collectively, "Awardees"). Awards include options, restricted shares, bonus shares, stock appreciation rights and performance shares (the "Awards"). The IDDS Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined. The IDDS Plan includes an automatic option grant program for non-employee directors, under which option grants will automatically be made at periodic intervals to non-employee board members to purchase shares of common stock as defined. The IDDS Plan provides for a Committee of the Board of Directors (the "Committee") to grant Awards to Awardees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the Awards, including acceleration of the vesting of an Award at any time. All options granted under the IDDS Plan are intended to be non-qualified ("NQO") unless specified by the Committee to be incentive stock options ("ISO"), as defined by the Internal Revenue Code. NQO's may be granted to employees, consultants or other individuals at an exercise price, equal to, below or above the fair value of the common stock on the date of grant. ISO's may only be granted to employees and may not be granted at exercise prices below fair value of the common stock on the date of grant (110% of fair value for employees who own 10% or more of the Company). The period during which an option may be exercised may not exceed ten years from the date of grant (five years for grants of ISO's to employees who own 10% or more of the Company). Under the IDDS Plan, for a period of one year following the termination of an Awardee's employment or active involvement with us, we have the right, should certain contingent events occur, to repurchase any or all shares of common stock acquired upon exercise of an Award held by the Awardee at a purchase price defined by the IDDS Plan. The IDDS Plan will terminate at the earliest of (i) its termination by the Committee, (ii) February 4, 2011 or (iii) the date on which all of the shares of common stock available for issuance under the Plan have been issued and all restrictions on such shares have lapsed. Awards granted before termination of the IDDS Plan will continue under the IDDS Plan until exercised, cancelled or expired.

Immediately prior to and as a condition of the Reverse Merger, we adopted the Intrac 2004 Omnibus Stock Incentive Plan (the "2004 Plan") covering the grant of stock options, restricted stock and other employee awards, subject to stockholder ratification. The terms of the 2004 Plan are substantially the same as the terms of the IDDS Plan. The 2004 Plan authorizes awards of up to 5,000,000 shares of common stock. Upon the closing of the Reverse Merger, the outstanding options under the IDDS Plan were exchanged for options under the 2004 Plan with the number of option shares and the exercise prices adjusted to reflect the merger exchange ratio (see Note 1). Our shareholders adopted the 2004 Plan at the annual Meeting of Shareholders on September 7, 2005.

Upon closing of the Migratory Merger, the Javelin 2005 Omnibus Plan (the "2005 Plan") became effective and the outstanding options under the 2004 Plan were exchanged for similar options under the 2005 Plan. The terms of the 2005 Plan are substantially the same as the 2004 Plan. On July 20, 2006, our shareholders approved an amendment to the 2005 Plan to increase the number of shares of common stock underlying the awards thereunder to 7,500,000 shares.

As of December 31, 2006, under the 2005 Plan, options for the purchase of an aggregate of 5,374,477 shares of common stock have been granted and are outstanding. The number of options remaining to be granted totals 2,125,523.

The following table summarizes stock option information for options granted under the 2005 Plan as of December 31, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$1.50 - \$1.90	711,969	5.1 years	\$ 1.53	678,636	\$ 1.51
\$1.91 - \$1.97	1,424,418	6.8 years	\$ 1.96	1,101,921	\$ 1.96
\$1.98 - \$2.80	705,250	7.2 years	\$ 2.70	463,584	\$ 2.69
\$2.81 - \$3.27	709,000	9.2 years	\$ 3.06	153,000	\$ 2.85
\$3.28 - \$3.87	735,921	9.0 years	\$ 3.59	84,254	\$ 3.67
\$3.88 - \$4.19	727,367	8.4 years	\$ 4.06	73,685	\$ 4.05
\$4.20 - \$5.40	360,552	3.4 years	\$ 5.37	360,552	\$ 5.37
<b>\$1.50 - \$5.40</b>	<b>5,374,477</b>	<b>7.2 years</b>	<b>\$ 2.88</b>	<b>2,915,632</b>	<b>\$ 2.54</b>

The following table summarizes stock option information for options granted under the 2005 Plan as of December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$1.50	661,969	7.2 years	\$ 1.50	661,969	\$ 1.50
\$1.90	50,000	9.5 years	\$ 1.90	-	-
\$1.96	1,451,743	8.1 years	\$ 1.96	704,912	\$ 1.96
\$1.97	6,620	8.5 years	\$ 1.97	6,620	\$ 1.97
\$2.60	50,000	9.5 years	\$ 2.60	-	-
\$2.70	635,750	9.3 years	\$ 2.70	150,000	\$ 2.70
\$2.80	75,000	9.2 years	\$ 2.80	-	-
\$2.85	260,000	9.7 years	\$ 2.85	75,000	\$ 2.85
\$3.05	9,000	9.6 years	\$ 3.05	-	-
\$3.33	75,000	9.6 years	\$ 3.33	-	-
\$3.45	25,000	9.7 years	\$ 3.45	-	-
\$3.87	50,921	6.7 years	\$ 3.87	50,921	\$ 3.87
\$5.36	309,631	4.1 years	\$ 5.36	309,631	\$ 5.36
\$5.40	50,921	6.3 years	\$ 5.40	50,921	\$ 5.40
<b>\$1.50 - \$5.40</b>	<b>3,711,555</b>	<b>8.0 years</b>	<b>\$ 2.49</b>	<b>2,009,974</b>	<b>\$ 2.56</b>

Transactions involving options granted under the 2005 Plan during the years ended December 31, 2004, 2005 and 2006 are summarized as follows:

	Number of shares	Weighted- Average Exercise Price	Number Exercisable	Weighted- Average Exercise Price
Balance outstanding, December 31, 2003	1,996,630	\$ 2.53	456,781	\$ 4.59
Granted	1,101,413	\$ 1.96	—	—
Exercised	—	—	—	—
Forfeited or expired	(385,468)	\$ 1.64	—	—
Balance outstanding, December 31, 2004	2,712,575	\$ 2.32	1,405,358	\$ 2.66
Granted	1,313,750	\$ 2.75	—	—
Exercised	—	—	—	—
Forfeited or expired	(314,770)	\$ 2.14	—	—
Balance outstanding, December 31, 2005	3,711,555	\$ 2.49	2,009,974	\$ 2.56
Granted	1,935,182	\$ 3.72	—	—
Exercised	—	—	—	—
Forfeited or expired	(272,260)	\$ 3.77	—	—
Balance outstanding, December 31, 2006	5,374,477	\$ 2.88	2,915,632	\$ 2.54

The deemed per share weighted average fair value of our common stock at the time of the stock option grant for the years ended December 31, 2006, 2005 and 2004 was \$2.50, \$1.84 and \$2.18, respectively, based upon the quoted market closing price on the date of the grant using the Black-Scholes method. The aggregate intrinsic values for options outstanding and exercisable as of December 31, 2006 were approximately \$12.5 million and \$7.7 million, respectively. Intrinsic value for stock options is calculated based on the difference between the exercise price of the underlying awards and the quoted price of our common stock as of the reporting date. The total fair value of 905,662 shares vesting during 2006 was approximately \$1.8 million.

As of December 31, 2006, the total compensation cost related to unvested option awards not yet recognized amounted to approximately \$4.0 million which will be recognized over a weighted average number of 2.0 years.

Included in the balance outstanding at December 31, 2003 were the following options granted to members of the Board: (i) 362,194 options on February 25, 2002, with an exercise price of \$5.36, approximately two-thirds of which were vested immediately with the remainder vesting through February 2003 and (ii) 50,921 options with an exercise price of \$5.40 on April 1, 2002, one-quarter vesting immediately and the remainder vesting over three years. On the dates of grant, the fair value of our common stock was deemed to be \$8.84 per share. Thus, in accordance with APB No. 25, we recorded unearned compensation of \$1,431,498, which was equal to the total intrinsic value of those options on the respective dates of grant. We amortized unearned compensation as compensation expense, respectively, over the respective vesting periods of the options. For the years ended December 31, 2004 and 2005, we recognized \$43,125 and \$10,782 of compensation expense respectively for those options.

Included in the options above, during the years ended December 31, 2000, 2002 and 2003 we granted 305,676 fully vested non-plan options, 50,921 fully vested options and 76,381 options vesting over one year under the Plan to non-employees ("Non-employee Options") with average exercise prices of \$3.87, \$5.36 and \$1.50, respectively, which are accounted for in accordance with EITF 96-18. The estimated fair values of the Non-employee Options on the grant dates in 2000 and 2002, totaling \$707,550 and \$62,564, respectively, were recognized as compensation expense in the years ended December 31, 2000 and 2002, respectively. During the year ended December 31, 2003, we recognized an expense of \$57,672, in connection with Non-employee Options.

During 2004, two consultants received a total of 6,620 options to purchase shares of common stock at an exercise price of \$1.97 per share. The options fully vested upon the first anniversary of the grant and expire in June 2014. As of December 31, 2004, we recognized \$14,498 of compensation expense for these options based upon their fair value as estimated by our management, at the grant date using the Black Scholes option pricing model. In addition, \$118,003 of compensation expense was recognized in connection with the Non-employee Option that had been granted in 2003.

During 2004, we granted a total of 1,094,793 stock options with an exercise price of \$1.96 per share to four employees and a Board member. The options had an exercise price of \$1.96 per share, and vest over three years. The deemed per share fair value of the common stock at the time of the stock option grant was \$2.95, based upon the sale of common stock to investors in December 2004 (see Note 6). Accordingly, unearned compensation of \$1,094,793, representing the intrinsic value of the options granted during 2004, was recorded. Such amount was amortized to compensation expense ratably over the respective vesting periods of the options. The total amortized compensation expense associated with the options granted in 2004 totaled \$155,227 for the year ended December 31, 2004 and 334,890 for the year ended December 31, 2005.

During 2005, one person and one entity received a total of 40,000 options to purchase shares of common stock at an exercise price of \$2.85 per share. The options were fully vested upon the grant date and expire in September 2015. As of December 31, 2005, we recognized \$95,200 of compensation expense for these options based upon their fair value as estimated by our management, at the grant date using the Black Scholes option pricing model.

*Non-Plan options*

In addition, as of December 31, 2006, we had outstanding 1,184,058 options which were granted to our Founders outside of the Javelin 2005 Plan, prior to the adoption of the IDDS Plan.

The following table summarizes non-plan stock option information for the options as of December 31, 2006:

	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Prices	Number Exercisable	Weighted Average Exercise Price
Range of Exercise Prices					
\$3.87	1,184,058	3.4 years	\$ 3.87	1,184,058	\$ 3.87

The following table summarizes non-plan stock option information for the options as of December 31, 2005:

	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Prices	Number Exercisable	Weighted Average Exercise Price
Range of Exercise Prices					
\$3.87	1,184,058	4.9 years	\$ 3.87	1,184,058	\$ 3.87

Transactions involving non-plan stock options during the years ended December 31, 2004, 2005 and 2006 are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
Balance outstanding, December 31, 2003	1,340,529	\$ 3.87	1,340,529	\$ 3.87
2004: Canceled	(155,230)	\$ 3.87	—	\$ 3.87
Balance outstanding, December 31, 2004	1,185,299	\$ 3.87	1,185,299	\$ 3.87
2005: Exercised	(1,241)	\$ 0.01	—	\$ 0.01
Balance outstanding, December 31, 2005 and 2006	1,184,058	\$ 3.87	1,184,058	\$ 3.87

**Pro-forma Disclosure**

The following table illustrates the effect on net loss and loss per share if we were to have applied the fair-value based method to account for all stock-based awards for 2005 and 2004:

	Year Ended December 31,	
	2005	2004
Net loss as reported	\$ (10,611,772)	\$ (7,046,828)
Add: Stock-based employee compensation included in net loss under APB No. 25	345,672	198,351
Deduct: Total stock-based employee compensation expense determined under fair value base method for all awards	(1,796,017)	(1,469,442)
Pro forma net loss	\$ (12,062,117)	\$ (8,317,919)
Proforma net loss per share (basic and diluted)	\$ (0.43)	\$ (0.76)

For the purposes of the above pro forma calculations, the fair value of each option granted was estimated on the date of grant using the Black Scholes option pricing model. The weighted-average fair value of all options granted during 2004 and 2005 was \$2.18 and \$1.84, respectively. The following table summarizes the assumptions used in computing the fair value of option grants.

Expected volatility	2005 80%	2004 80%
Expected life	5	5
Dividend yield	0%	0%
Risk free interest rate	3.4 - 4.5%	4.5%

Prior to 2006, the fair value of options and warrants granted to non-employees for financing, goods or services are included in the financial statements and expensed over the life of the debt, as the goods are utilized or the services performed, respectively. Securities issued in connection with services or financings were valued based upon the estimate of fair value of the securities issued as determined using the Black Scholes option pricing model with the assumptions noted above. Such fair value was determined at each balance sheet date through the vesting period, in accordance with Emerging Issues Task Force No. 96-18 Accounting for Equity Instruments that are issued to other than employees for acquiring, or in conjunction with selling goods or services ("EITF 96-18").

## 11. Warrants and Units

The following table summarizes warrant and unit activity for the period from February 23, 1998 (inception) to December 31, 2006:

	Placement Warrants	Debenture Warrants	Bridge Warrants	Investor Warrants	Consultants Warrants	Finders Units
Issuance of Bridge Warrants (see Note 7)			236,127			
Issuance of Consultants Warrants (see Note 7)					204,336	
Balance outstanding, December 31, 1999	—	—	236,127	—	204,336	—
Issuance of Preferred A Warrants (see Note 6)				415,403		
Exercise of Consultants Warrants					(204,336)	
Issuance of Finders Units (see Note 6)						15.83 (1)
Issuance of Consultants Warrants (see Note 6)					15,523	
Balance outstanding, December 31, 2000	—	—	236,127	415,403	15,523	15.83
Exercise of Bridge Warrant			(15,893)			
Exercise of Consultants Warrants					(15,523)	
Balance outstanding, December 31, 2001 and 2002	—	—	220,234	415,403	—	15.83
Exercise of Bridge Warrants (see Note 7)			(2,270)			
Balance outstanding, December 31, 2003	—	—	217,964	415,403	—	15.83
Issuance of Debenture Warrants (see Note 7)		226,314				
Issuance of Placement Warrants (see Note 6)	920,987					

	Placement Warrants	Debenture Warrants	Bridge Warrants	Investor Warrants	Consultants Warrants	Finders Units
Balance outstanding, December 31, 2004	920,987	226,314	217,964	415,403	—	15.83
Exercise of Bridge and Investor Warrants			(217,964)	(26,518)		
Expiry of Preferred A Warrant (see Note 6)				(388,885)		
Issuance of Consultants Warrants (see Note 6)					80,184	
Issuance of 2005 Investor Warrants (see Note 6)				711,111		
Issuance of 2005 Placement Warrants (see Note 6)	853,333					
Balance outstanding, December 31, 2005	1,774,320	226,314	—	711,111	80,184	15.83
Exercise of 2005 Investor Warrants				(4,444)		
Balance outstanding, December 31, 2006	1,774,320	226,314	—	706,667	80,184	15.83

- (1) Each Finders Unit entitles the holder to purchase 28,459 shares of common stock. Total issuance entitles holders to purchase 450,506 shares common stock.

See Note 10 for the description of the method and assumptions used to determine the fair value of the warrants issued.

## 12. Related Party Transactions

From our inception, through the year ended December 31, 2002, we received financial assistance from a principal stockholder in the form of office space and management and legal assistance provided at no cost. In accordance with the Staff Accounting Bulletin No. 79, the value of such assistance has been reflected in the accompanying financial statements as an expense in the period benefited with a corresponding deemed capital contribution. The value of the financial assistance totaled \$1,075,182 for the cumulative period from February 23, 1998 (inception) to December 31, 2002.

## 13. Income Taxes

There is no net provision (benefit) for federal or state income taxes for the years ended December 31, 2006, 2005 and 2004 since we have incurred operating losses and have established valuation allowances equal to the total deferred tax asset due to the uncertainty with respect to achieving taxable income in the future.

The tax effect of temporary differences and net operating losses as of December 31, 2006 and 2005 are as follows:

	December 31, 2006	December 31, 2005
Deferred tax assets and valuation allowance:		
Net operating loss carry forwards	\$ 20,230,000	\$ 12,969,000
Other deferred tax assets	5,127,000	3,612,000
Research and development tax credit carryforwards	2,882,000	1,970,000
Valuation allowance	(28,239,000)	(18,551,000)
	<u>—</u>	<u>—</u>

Our effective tax rates for 2006, 2005 and 2004 are calculated as follows:

	2006		2005		2004	
	Amount	Percent	Amount	Percent	Amount	Percent
Pre tax income (loss)	<u>\$ (17,798,236)</u>		<u>\$ (10,611,772)</u>		<u>\$ (7,046,828)</u>	
Federal tax provision (benefit) at statutory rate	(6,051,400)	34.0%	(3,608,002)	34.0%	(2,395,922)	34.0%
State income tax benefit net of federal tax benefit	(1,834,003)	10.3%	(748,462)	7.1%	(722,216)	10.2%
Permanent differences	382,663	-2.2%	427,039	-4.0%	163,617	-2.2%
R & D credit	(1,108,705)	6.3%	(776,328)	7.3%	(432,225)	6.1%
Change in valuation allowance	9,688,000	-54.4%	3,679,000	-34.7%	3,510,000	-49.8%
Change in rate	—	—%	911,066	-8.6%	—	0.0%
Other	(1,076,555)	6.0%	115,687	-1.1%	(123,254)	1.7%
Total income tax provision / (benefit)	<u>\$ 0</u>	<u>0.0%</u>	<u>\$ 0</u>	<u>0.0%</u>	<u>\$ 0</u>	<u>0.0%</u>

#### 14. Other Income

Other income consists primarily of \$1.3 million of interest income for interest earned on our cash, cash equivalents and short term marketable securities available for sale. For the year ended December 31, 2006 we had higher average invested balances of cash, cash equivalents and short term investments than in 2005. Additionally, in February 2006, we settled litigation with West Pharmaceutical Services, Inc. ("West") regarding West's assignment of certain license agreements to Archimedes Pharma Limited ("Archimedes") as part of the sale West's Drug Delivery business to Archimedes. Under the terms of the settlement, on March 1, 2006 West paid us approximately \$600,000 to resolve all claims, and the parties exchanged mutual releases; this amount is included in other income for the year ended December 31, 2006.

#### 15. Subsequent Events

On February 6, 2007, we filed with the SEC a Registration Statement on Form S-3 under the Securities Act, which became effective on February 12, 2007. This registration statement allows us, from time to time, to offer and sell shares, and warrants to purchase shares, of our common stock, but not to exceed \$50,000,000. To date, we have not issued any additional shares or warrants under this registration statement.

#### SUPPLEMENTARY FINANCIAL INFORMATION (UNAUDITED)

The following tables set forth unaudited quarterly operating results for fiscal years 2006 and 2005 in dollars. The information in these tables has been prepared on a basis consistent with the audited consolidated financial statements included elsewhere in this report and, in the opinion of management, all adjustments that management considers necessary for the fair presentation thereof. These unaudited results should be read in conjunction with the consolidated financial statements and notes appearing elsewhere in this report. The sum of the quarterly loss per share may not total annual amounts reported in the consolidated financial statements as a result of any quarterly changes in the amount of weighted average common shares used in the calculation of basic and diluted loss per share.

#### 2006 Quarterly results of operations

(In thousands, except per share data)	Unaudited Quarter ended			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
Government grants and contract revenue	\$ 82	\$ 491	\$ 155	\$ 114
Operating expenses				
Research and development	1,324	3,013	3,694	2,823
Selling, general and administrative	1,688	2,310	2,484	3,127
Depreciation and amortization	11	13	17	20
Operating loss	(2,941)	(4,845)	(6,040)	(5,856)
Other income (expense)	916	315	343	310
Net loss attributable to common stockholders	<u>(2,025)</u>	<u>(4,530)</u>	<u>(5,697)</u>	<u>(5,546)</u>
Net loss per share attributable to common stockholders:				
Basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.11)</u>	<u>\$ (0.14)</u>	<u>\$ (0.14)</u>
Weighted average shares	<u>40,178</u>	<u>40,178</u>	<u>40,180</u>	<u>40,182</u>



**Changes in Internal Control over Financial Reporting.** There were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during our fourth fiscal quarter of 2006.

## ITEM 9B. OTHER INFORMATION

We filed Forms 8-K for the fourth quarter of fiscal 2006 disclosing therein all information required to be disclosed in a Form 8-K during that fiscal quarter.

## PART III.

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

### Executive Officers and Directors

As of December 31, 2006, our executive officers and directors were:

Name	Age	Position
Douglas G. Watson (1)(2)(3)	61	Chairman of the Board and Director
Daniel B. Carr, M.D.	58	Chief Executive Officer, Chief Medical Officer and Director
Fred H. Mermelstein, Ph.D.	47	President and Director
Stephen J. Tulipano	47	Chief Financial Officer
David B. Bernstein	44	Secretary, General Counsel and Chief Intellectual Property Counsel
Jackie M. Clegg (1)(2)(3)	44	Director
Martin J. Driscoll (3)	47	Director
Neil W. Flanzraich (1)	63	Director
Georg Nebgen, Ph.D.	45	Director

1. Member of Audit Committee
2. Member of Compensation Committee
3. Member of Corporate Governance Committee

Each director serves for a staggered three-year term, with one class of directors standing for election each year. The terms expire at the following annual meeting of stockholders: 2007 – Class II — Drs. Carr and Mermelstein; 2008 – Class III — Ms. Clegg and Mr. Driscoll; and 2009 – Class I – Messrs. Watson, Flanzraich and Nebgen.

The principal occupations and brief summary of the background of each director and executive officer is as follows:

### **Class I Directors**

**Douglas G. Watson** has served as our Chairman of the Board and a director since December 2004, and as a director of IDDS since April 2002. He is the Chief Executive Officer of Pittencrieff Glen Associates, a consulting company, which he founded in June 1999. From January 1997 to June 1999, Mr. Watson served as President, Chief Executive Officer and a director of Novartis Corporation, the U.S. subsidiary of Novartis A.G. Mr. Watson serves as Chairman of OraSure Technologies, Inc. [Nasdaq: OSUR], as a director of Engelhard Corporation, [NYSE:EC], Genta Inc. [Nasdaq:GNTA], and Dendreon Corporation [Nasdaq:DNDN], as well as BioElectronics Inc. and InforMedix Inc. Mr. Watson is the chairman of Freedom House Foundation and a director of the American Liver Foundation. Mr. Watson holds an M.A. in Mathematics from Churchill College, Cambridge University. He is also a member of the Chartered Institute of Management Accountants.

**Neil W. Flanzraich** has served as a director since June 2006. He has been a private investor since February 2006. From 1998 through its sale in January 2006 to TEVA Pharmaceuticals Industries, Ltd., he served as Vice Chairman and President of IVAX Corporation, an international pharmaceutical company. From 1995 to 1998, Mr. Flanzraich served as Chairman of the Life Sciences Legal Practice Group of Heller Ehrman LLP, a law firm, and from 1981 to 1994, was Senior Vice President and member of the Corporate Operating Committee at Syntex Corporation, a pharmaceutical company. He is also a Director of Equity One Inc. [NYSE:EQY], Continucare Corporation [ASE:CNU], RAE Systems, Inc. [ASE:RAE], and Neurochem Inc. [Nasdaq:NRMX]. He also serves as Chairman of the Israel America Foundation. Mr. Flanzraich received an A.B. from Harvard College and a J.D. from Harvard Law School.

**Georg Nebgen, Ph.D.** has served as a director since December 8, 2006. From 2003 until the present, Dr. Nebgen served as a managing member and co-founder of NGN Capital, LLC, which is the indirect general partner of NGN Biomed Opportunity I, L.P. and the managing limited partner of NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG (collectively, "NGN Capital"), each of which is a shareholder of our company. Prior to his appointment as a director, Dr. Nebgen had acted as the designee of NGN Capital in attending Board meetings as an observer since November 2005. Before joining NGN Capital, Dr. Nebgen had been a principal at MPM Capital in Boston and Managing Director of MPM GmbH. Prior to that, Dr. Nebgen served with Schering-Plough Corporation as Managed Care Area Manager in New England. His responsibilities included contracting the reimbursement of Schering-Plough's ethical pharmaceutical products and services with managed care organizations, as well as leading sales pull-through activities of the field forces. Dr. Nebgen obtained his doctorate in Pharmaceutical Technology Sciences from the University of Bonn, Germany and his executive MBA from the University of St. Gallen, Switzerland.

#### **Class II Directors**

**Daniel B. Carr M.D.** has served as our Chief Executive Officer since July 2005, a director since December 2004 and our Chief Medical Officer since September 2004 when he joined IDDS from his position as Saltonstall Professor of Pain Research at Tufts-New England Medical Center, and Professor of Anesthesiology and Medicine. He had held both positions since 1994. He ended his clinical responsibilities effective September 2004. From 1995 to 2003, he was the Medical Director of the Pain Management Program at the New England Medical Center, which merged into the Pain Management program at Caritas St. Elizabeth's Medical Center, another Tufts-affiliated program. Dr. Carr was a founder of the Pain Center at the Massachusetts General Hospital and served as Special Consultant to the U.S. Department of Health and Human Services and Co-Chair of the Agency for Health Care Policy and Research's Clinical Practice Guidelines on Acute and Cancer Pain Management. He is Editor-in-Chief of Pain: Clinical Updates published by the International Association for the Study of Pain ("IASP"), and has served as a Director of the American Pain Society and the IASP. Dr. Carr holds a bachelors degree from Columbia College and an M.D. degree from Columbia University College of Physicians and Surgeons.

**Fred Mermelstein, Ph.D.** has served as our President and a director since December 2004, having been our Chief Executive Officer from December 2004 through June 2005 and Secretary from December 2004 to April 2006, and had served as a director of IDDS and as its President from inception in February 1998 through July 2003 when he also became Chief Executive Officer. From April 1996 to July 2003, he was employed by Paramount Capital Investments, LLC where he became a Director of Venture Capital and a member of Orion Biomedical GP, LLC. He currently serves as a director of Cardiome Pharma Corp. [Nasdaq:CRME] and Adherex Technologies, Inc. [ASE:ADH]. From February 1997 until January 2000, Dr. Mermelstein was founder and served as a director and the Chief Scientific Officer of PolaRx BioPharmaceuticals, an oncology-based biopharmaceutical company. Dr. Mermelstein also serves on the scientific advisory board of Cardiome Pharma Corp. Dr. Mermelstein holds a dual Ph.D. in Pharmacology and Toxicology from Rutgers University and University of Medicine and Dentistry of New Jersey ("UMDNJ") Robert Wood Johnson Medical School. He completed his post-doctoral training supported by two grant awards, a National Institutes of Health fellowship and a Howard Hughes Medical Institute fellowship in the Department of Biochemistry at UMDNJ Robert Wood Johnson Medical School.

#### **Class III Directors**

**Jackie M. Clegg** has served as a director since December 2004, and as a director of IDDS since February 2004. In September 2001, she formed the international strategic consulting firm Clegg International Consultants, LLC ("CIC") specializing in emerging markets. From May 1997 to July 2001, Ms. Clegg served as Vice Chair of the Board of Directors and First Vice President of the Export-Import Bank of the United States ("Ex-Im Bank"), having previously served in various positions from 1993 to 1997 at Ex-Im Bank, including Chief of Staff. Prior to joining Ex-Im Bank, Ms. Clegg worked for ten years in the United States Senate on the staff of both the Banking and the Appropriations Committees. Ms. Clegg is also currently serving as a director of Blockbuster Inc. [NYSE: BBI], Brookdale Senior Living, Inc. [NYSE: BKD], The Chicago Board of Trade [NYSE: BOT] and Cardiome Pharma Corp. [Nasdaq: CRME].

**Martin J. Driscoll** has served as a director since June 2006. He has been a principal of MJD Consulting LLC, a pharmaceutical marketing company, since 2005, and was a principal of that firm from its founding in 2002 to 2003. From 2003 to 2005, Mr. Driscoll was Senior Vice President of Sales and Marketing at Reliant Pharmaceuticals, a privately-held company that markets a portfolio of branded pharmaceutical products. From 2000 to 2002, Mr. Driscoll was Vice President, Commercial Operations and Business Development at ViroPharma, Inc. From 1983 to 2000, he held various positions at Schering Plough Corporation, including Vice President of Sales and Marketing for its Primary Care Division, and Vice President, Sales and Marketing for the Schering Diabetes Unit. He is a Director of Genta Incorporated (Nasdaq:GNTA). Mr. Driscoll received a B.S. from the University of Texas.

## Executive Officers

In addition to Daniel B. Carr, M.D., our Chief Executive Officer and Chief Medical Officer, and Fred H. Mermelstein, Ph.D., our President, each of whom is a member of our Board of Directors and, consequently, is summarized above, our executive officers are as follows:

**Stephen J. Tulipano** has served as our Chief Financial Officer since May 1, 2006. From October 1998 to April 2006, he was employed by Biogen Idec Inc., in various capacities, beginning with External Reporting Manager in October 1998, Associate Director of Corporate Accounting in April 2001 and most recently as Director of Corporate Accounting from December 2002 to April 2006. During his tenure at Biogen Idec, Mr. Tulipano was responsible for establishing new accounting and internal controls initiatives worldwide and developing innovative business approaches to partnered programs and business development opportunities. Prior thereto, from January 1996 to September 1998, he was External Reporting Manager at Digital Equipment Corporation. Mr. Tulipano is a Certified Public Accountant, is a member of the American Institute of Certified Public Accountants and the Massachusetts Society of Certified Public Accountants, and holds an M.B.A. from Suffolk University.

**David B. Bernstein** has served as our Secretary, General Counsel and Chief Intellectual Property Counsel since April 2006. From November 2000 to March 2006, he served as General Counsel and Chief Intellectual Property Counsel at U.S. Genomics, Inc. From September 1997 to October 2000, he was a partner at Mintz Levin Cohn Ferris Glovsky & Popeo where he co-founded and chaired the Intellectual Property department. Mr. Bernstein holds a J.D. from Franklin Pierce Law Center and a B.S. in Engineering Science (Chemical) from Yale University.

There is no family relationship among our officers and directors. Dr. Mermelstein and Ms. Clegg both serve on the Board of Directors of Cardiome Pharma Corp., and Mr. Watson and Mr. Driscoll both serve on the Board of Directors of Genta Incorporated.

## Corporate Governance

### Board Composition

Our board of directors is currently composed of seven members. Messrs. Watson, Flanzraich and Driscoll, and Ms. Clegg, qualify as independent directors in accordance with the published listing requirements of the American Stock Exchange. The American Stock Exchange independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as further required by the American Stock Exchange rules, our board of directors has made an affirmative determination as to each independent director that no relationships exist which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities as they may relate to us and our management. Our directors hold office until their successors have been elected and qualified or their earlier death, resignation or removal.

### Board Committees

Our Board of Directors currently has three standing committees which, pursuant to delegated authority, perform various duties on behalf of and report to the Board: (i) Audit Committee, (ii) Compensation Committee and (iii) Corporate Governance and Nominating Committee. From time to time, the Board may establish other committees.

The Audit Committee is responsible for: (i) overseeing the corporate accounting and financial reporting practices; (ii) recommending the selection of our registered public accounting firm; (iii) reviewing the extent of non-audit services to be performed by the auditors; and (iv) reviewing the disclosures made in our periodic financial reports. The members of the Audit Committee are Jackie M. Clegg, Douglas G. Watson and Neil W. Flanzraich, each of whom is an independent director within the meaning of the rules of the American Stock Exchange and Rule 10A-3 promulgated by the SEC under the Exchange Act. In addition, the Board of Directors has determined that each member of the Audit Committee qualifies as an Audit Committee Financial Expert under applicable SEC Rules. The Chairman of the Audit Committee is Ms. Clegg.

The Compensation Committee determines matters pertaining to the compensation of executive officers and other significant employees, and administers our stock and incentive plans. The members of the Compensation Committee are Douglas G. Watson and Jackie M. Clegg. The Chairman of the Compensation Committee is Mr. Watson.

The Corporate Governance and Nominating Committee establishes internal corporate policies and nominates persons to serve on our Board of Directors. The members of the Corporate Governance and Nominating Committee are Douglas G. Watson, Jackie M. Clegg and Martin J. Driscoll. The Chairman of the Corporate Governance and Nominating Committee is Mr. Watson.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities ("Reporting Persons"), to file reports of ownership and changes in ownership with the SEC and with the American Stock Exchange. The Reporting Persons are also required to furnish us with copies of all such reports. Based solely on our review of the reports received by us, and written representations from certain Reporting Persons that no other reports were required for those persons, we believe that, during the year ended December 31, 2006, the Reporting Persons met all applicable Section 16(a) filing requirements.

### Code of Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our employees and officers, and the members of our Board of Directors. The Code of Conduct and Ethics is available on our website at [www.javelinpharmaceuticals.com](http://www.javelinpharmaceuticals.com). Printed copies are available upon request without charge. Any amendment to or waiver of the Code of Conduct and Ethics will be disclosed on our website promptly following the date of such amendment or waiver.

## ITEM 11. EXECUTIVE COMPENSATION

### Compensation Discussion and Analysis

The Board of Directors, the Compensation Committee and senior management share responsibility for establishing, implementing and continually monitoring our executive compensation program, with the Board making the final determination with respect to executive compensation. The goal of our executive compensation program is to provide a competitive total compensation package to our executive management team through a combination of base salary, annual cash incentive bonuses, long-term equity incentive compensation and broad-based benefits programs. This Compensation Discussion and Analysis explains our compensation objectives, policies and practices with respect to our Chief Executive Officer, Chief Financial Officer and certain of our other most highly-compensated executive officers as determined in accordance with applicable SEC rules, which are collectively referred to herein as the Named Executive Officers.

#### *Objectives of Our Executive Compensation Program*

Our executive compensation program is designed to achieve the following objectives:

- attract and retain talented and experienced executives in the highly competitive and dynamic pharmaceutical industry;
- motivate and reward executives whose knowledge, skills and performance are critical to our success;
- align the interests of our executives and stockholders by motivating executives to increase stockholder value;
- provide a competitive compensation package in which a significant portion of total compensation is determined by company and individual results and the creation of stockholder value; and
- foster a shared commitment among executives by coordinating their company and individual goals.

#### *Our Executive Compensation Program*

Our executive compensation consists of base salary, annual cash incentive bonuses, long-term equity incentive compensation and broad-based benefits programs. Consistent with the emphasis we place on performance-based incentive compensation, cash incentive bonuses and long-term equity incentive compensation in the form of stock options constitute a significant portion of our total executive compensation. We structured our annual cash incentive bonuses to be primarily tied to the achievement of predetermined company and individual performance goals, which are established at the beginning of each year (or in the case of Named Executive Officers who have commenced employment during the applicable fiscal year, at the time of their engagement by our company), on an individualized basis.

Within the context of the overall objectives of our compensation program, we determined the specific amounts of compensation to be paid to each of our executives in 2006 based on a number of factors including:

- our understanding of the amount of compensation generally paid by similarly situated companies to their executives with similar roles and responsibilities;
- our executives' performance during 2006 in general and as measured against predetermined company and individual performance goals;
- the roles and responsibilities of our executives;
- the individual experience and skills of, and expected contributions from, our executives;

- the amounts of compensation being paid to our other executives;
- our executives' historical compensation and performance at our company; and
- any contractual commitments we have made to our executives regarding compensation.

Each of the primary elements of our executive compensation is discussed in detail below, including a description of the particular element and how it fits into our overall executive compensation. In the descriptions below, we highlight particular compensation objectives that we have designed our executive compensation program to address. However, it should be noted that we have designed the various elements of our compensation program to complement each other and thereby collectively serve all of our executive compensation objectives. Accordingly, whether or not specifically mentioned below, we believe that each element of our executive compensation program, to a greater or lesser extent, serves each of our compensation objectives.

### ***Base Salary***

Our approach is to pay our executives a base salary that is competitive with those of other executive officers in our peer group of competitive companies. We believe that a competitive base salary is a necessary element of any compensation program that is designed to attract and retain talented and experienced executives. We also believe that attractive base salaries can motivate and reward executives for their overall performance. The base salary of each Named Executive Officer is reviewed annually, and may be increased or decreased in accordance with the terms of such executive officer's employment agreement, where applicable, and certain performance criteria, including, without limitation: (i) individual performance; (ii) our performance as a company; (iii) the functions performed by the executive officer; and (iv) changes in the compensation peer group in which we compete for executive talent. Discretion is used to determine the weight given to each of the factors listed above and such weight may vary from individual to individual. Evaluations of base salary are made regardless of whether a Named Executive Officer has entered into an employment agreement with us, and while the base salary set forth in such employment agreement is taken into consideration, it is not dispositive of the base salary of such executive officer for a given year. Although evaluations of and recommendations as to base salary are made by the Compensation Committee and senior management, the ultimate determination is made by the Board of Directors.

In 2006, the base salary of each of Dr. Carr and Dr. Mermelstein remained at \$350,000 and \$228,000, respectively. Mr. Hamilton resigned from his positions with us effective May 2006, and received a base salary of \$88,125. Messrs. Tulipano and Bernstein commenced employment during the 2006 fiscal year, and received a base salary of \$133,333 and \$153,125, respectively. Going forward, Mr. Tulipano's employment agreement and Mr. Bernstein's term sheet provide for an annual base salary of \$200,000 and \$210,000, respectively. To the extent that we have entered into employment agreements with any of our Named Executive Officers, the base salaries of such individuals reflect the initial base salaries that we negotiated with them at the time of their initial employment or promotion and our subsequent adjustments to these amounts to reflect market increases, the growth and stage of development of our company, our executives' performance and increased experience, any changes in our executives' roles and responsibilities and other factors. The initial base salaries that we negotiated with our executives were based on our understanding of base salaries for comparable positions at similarly situated companies at the time, the individual experience and skills of, and expected contribution from, each executive, the roles and responsibilities of the executive, the base salaries of our existing executives and other factors.

### ***Annual Cash Incentive Bonuses***

Consistent with our emphasis on performance incentive compensation programs, our executives are eligible to receive annual cash incentive bonuses primarily based upon their performance as measured against predetermined company and individual goals covering clinical and regulatory operations, business development/commercialization, and corporate and financial achievements. These goals are recommended by senior management to the Compensation Committee, and then by the Compensation Committee to the Board of Directors, at the beginning of each year. The goals are ultimately set by the Board of Directors. If a Named Executive Officer joined our company during a particular year, these performance goals are established at the time of employment. The primary objective of our annual cash incentive bonuses is to motivate and reward our Named Executive Officers for meeting our short-term objectives using a performance-based compensation program with objectively determinable goals that are specifically tailored for each executive. In addition, we reserve a portion of each executive's annual cash incentive bonus to be paid at our discretion based on the executive's overall performance. We maintain this discretionary portion of the annual cash incentive bonuses in order to motivate our executives' overall performance and their performance relating to matters that are not addressed in the predetermined performance goals that we set. We believe that every important aspect of executive performance is not capable of being specifically quantified in a predetermined objective goal. For example, events outside of our control may occur after we have established the executives' performance goals for the year that require our executives to focus their attention on different or other strategic objectives.

We establish the target amount of our annual cash incentive bonuses at a level that represents a meaningful portion of our executives' currently paid out cash compensation, and set additional threshold and maximum performance levels above and below these target levels. In establishing these levels, in addition to considering the incentives that we want to provide to our executives, we also consider the bonus levels

for comparable positions at similarly situated companies, our historical practices and any contractual commitments that we have relating to executive bonuses.

Based upon the employment agreements that they have entered into with us, Dr. Carr is entitled to an annual bonus of up to \$320,000 (or options to purchase 200,000 shares of common stock, at the option of the Board), Mr. Tulipano is entitled to an annual bonus of up to 49% of his base salary (with 30% of his base salary as the target bonus), and Mr. Bernstein is entitled to an annual bonus of up to 30% of his base salary (plus up to 75,000 options). Because Messrs. Tulipano and Bernstein joined our company midway through the year, their entire bonus for 2006 was prorated to reflect the portion of the year that they worked for us. For the 2006 fiscal year, Messrs. Carr, Tulipano and Bernstein received a bonus of \$180,000, \$64,125 and \$45,300, respectively. For Dr. Mermelstein and Mr. Hamilton, with whom we have not entered into employment agreements, we established a bonus range of up to 89% and 49% of base salary, respectively. For the 2006 fiscal year, Dr. Mermelstein and Mr. Hamilton received a bonus of \$90,706 and \$55,000, respectively. Mr. Hamilton's bonus was paid pursuant to the letter agreement that he entered into with us in connection with his resignation as an officer of our company. As noted above, the amount of the bonus paid to each Named Executive Officer, regardless of whether or not they have entered into an employment agreement with us, reflects the extent to which such executive achieved the milestones established at the beginning of the year, plus the amount of the discretionary bonus that is based on our assessment of their overall performance during the year.

Overall, the targets for the performance measures were set at levels that we believed to be achievable with strong performance by our executives. Although we cannot always predict the different events that will impact our business during an upcoming year, we set our performance goals for the target amount of annual incentive cash bonuses at levels that we believe will be achieved by our executives a majority of the time. Our maximum and threshold levels for these performance goals are determined in relation to our target levels, are intended to provide for correspondingly greater or lesser incentives in the event that performance is within a specified range above or below the target level, and are correspondingly easier or harder to achieve. We set the performance goals for the maximum amount at a level that we believe will be achieved in some years, but will not be achieved a majority of the time. At the end of each year, the Compensation Committee evaluates the performance of each executive officer and provides to the Board its recommendation for the amount of the cash incentive bonus to be paid to each such executive for that year, with the Board making the final determination as to the amount of the cash incentive bonus.

### *Long-Term Equity Incentive Compensation*

We believe that long-term company performance is best achieved through an ownership culture that encourages long-term performance by our executive officers through the use of stock-based awards. We grant stock options in order to provide certain executive officers with a competitive total compensation package and to reward them for their contribution to our long-term growth in value and the long-term price performance of our common stock. Grants of stock options are designed to align the executive officer's interest with that of our stockholders. To assist us in retaining executives and encouraging them to seek long-term appreciation in the value of our stock, the benefits of the awards generally are not immediately realizable by the grantee as the awards vest over a specified period, usually three years, and therefore an employee must remain with us for a specified period to enjoy the full potential economic benefit of an award. We may consider as one of a number of factors the level of an executive officer's realizable compensation from awards granted in prior years when making decisions with respect to awards to be granted to that executive officer for the most recently ended fiscal year.

Based on the early stage of our company's development and the incentives we are trying to provide to our executives, we have currently chosen to use stock options, which derive value exclusively from increases in stockholder value, as opposed to restricted stock or other forms of equity awards. Our decisions regarding the amount and type of long-term equity incentive compensation and relative weighting of these awards among total executive compensation have also been based on our understanding of market practices of similarly situated companies and our negotiations with our executives in connection with their initial employment or promotion by us.

In addition to annual performance-based grants of stock options, we also granted options to certain of our Named Executive Officers at the time of their hiring as an incentive to accept employment with us. For instance, we granted as a hiring bonus to Dr. Carr options to purchase up to 900,000 shares of common stock, and to each of Messrs. Tulipano and Bernstein options to purchase up to 150,000 shares of common stock. These stock options vest in equal annual installments over three years. We previously had granted founder's options to each of Dr. Mermelstein and Mr. Hamilton.

Stock option awards provide our executive officers with the right to purchase shares of our common stock at a fixed exercise price typically for a period of up to ten years, subject to continued employment with our company. Stock options are earned on the basis of continued service to us and generally vest over three years, beginning with one-third vesting one year after the date of grant, then pro-rata vesting annually thereafter. Such vesting is intended as an incentive to such executive officers to remain with us and to provide a long-term incentive. Such options are generally exercisable, however, after termination of employment (other than termination for cause) if vested. We do not require that any portion of the shares acquired be held until retirement, we do not have a policy prohibiting a director or executive officer from hedging the economic risks of his or her stock ownership and we do not have any minimum stock ownership requirements for executive officers and directors. However, each of our executive officers has a significant number of exercisable options. Stock option awards are made pursuant to the Javelin 2005 Omnibus Stock Incentive Plan (the "2005 Plan"). See "Payments Upon Termination or Change-in-

Control" for a discussion of the change-in-control provisions related to stock options. The exercise price of each stock option granted under the 2005 Plan is based on the fair market value of our common stock on the grant date.

Awards granted under the 2005 Plan are based on a number of factors, including: (i) the grantee's position with us; (ii) his or her performance and responsibilities; (iii) the extent to which he or she already holds an equity stake with us; (iv) equity participation levels of comparable executives at other companies in the compensation peer group; and (v) individual contribution to the success of our financial performance. However, the 2005 Plan does not provide any formulated method for weighing these factors, and a decision to grant an award is based primarily upon the evaluation by the Compensation Committee, in consultation with senior management and the Board of Directors, of the past as well as the anticipated future performance and responsibilities of the individual in question. Awards to executive officers are first reviewed and approved by the Compensation Committee, which then makes a recommendation for final approval by our Board of Directors. Other than grants to newly-hired employees, option grants are generally planned to be awarded in January of each year at the regularly scheduled meetings of the Compensation Committee and the Board of Directors.

### *Other Compensation*

We maintain broad-based benefits that are provided to all employees, including health insurance, life and disability insurance, dental insurance and a 401(k) plan. In certain circumstances, on a case-by-case basis, we have used cash signing bonuses, which may have time-based forfeiture terms, when certain executives and senior non-executives have joined us. We do not provide any special reimbursement for perquisites, such as country clubs, automobiles, corporate aircraft, living or security expenses, for our employees or for any executive officers.

*Pension Benefits.* We do not offer qualified or non-qualified defined benefit plans to our executive officers or employees. In the future, we may elect to adopt qualified or non-qualified defined benefit plans if we determine that doing so is in our best interests.

*Nonqualified Deferred Compensation.* None of our Named Executive Officers participates in or has account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by us. To date, we have not had a significant reason to offer such non-qualified defined contribution plans or other deferred compensation plans. In the future, we may elect to provide our executive officers or other employees with non-qualified defined contribution or deferred compensation benefits if we determine that doing so is in our best interests.

*Severance and Change of Control Arrangements.* As discussed more fully in the section below entitled "Employment Agreements," certain of our executive officers are entitled to certain benefits upon the termination of their respective employment agreements. The severance agreements are intended to mitigate some of the risk that our executive officers may bear in working for a developing company such as ours.

*Policies Regarding Tax Deductibility of Compensation.* Within our performance-based compensation program, we aim to compensate the Named Executive Officers in a manner that is tax-effective for us. Section 162(m) of the Internal Revenue Code restricts the ability of publicly-held companies to take a federal income tax deduction for compensation paid to certain of their executive officers to the extent that compensation exceeds \$1.0 million per covered officer in any fiscal year. However, this limitation does not apply to compensation that is performance-based. The non-performance-based compensation paid in cash to our executive officers in the 2006 fiscal year did not exceed the \$1.0 million limit per officer, and we do not anticipate that the non-performance-based compensation to be paid in cash to our executive officers in 2007 will exceed that limit.

## Summary of Executive Compensation

The following table sets forth certain information concerning all cash and non-cash compensation awarded to, earned by or paid to our Chief Executive Officer, our Chief Financial Officer, and certain of our other executive officers (the "Named Executive Officers"), during the fiscal year ended December 31, 2006:

### SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(9)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Daniel B. Carr, M.D. – Chief Executive Officer and Chief Medical Officer	2006	\$350,000	—	—	\$688,602	\$180,000(3)	—	—	\$1,218,602
Stephen J. Tulipano, Chief Financial Officer (1)	2006	\$133,333	—	—	\$74,751	\$64,125(4)	—	—	\$272,209
Douglas A. Hamilton, Chief Financial Officer (2)	2006	\$88,125	—	—	\$37,099	\$55,000(5)	—	\$277,044(10)	\$457,268
Fred H. Mermelstein, PhD, President	2006	\$228,000	—	—	\$206,041	\$90,706(6)	—	—	\$524,747
David B. Bernstein, Secretary, General Counsel and Chief Intellectual Property Counsel (8)	2006	\$153,125	—	—	\$76,343	\$45,300(7)	—	—	\$274,768

- (1) Mr. Tulipano's term as Chief Financial Officer commenced on May 1, 2006.
- (2) Mr. Hamilton resigned as Chief Financial Officer effective May 1, 2006, and as Chief Operating Officer, Principal Financial Officer and Principal Accounting Officer effective May 12, 2006.
- (3) Dr. Carr is entitled to receive certain incentive compensation at the discretion of the Board of Directors, up to \$320,000 per year (or options to purchase up to 200,000 shares of common stock, at the option of the Board), if certain performance targets are met, pursuant to his employment agreement.
- (4) Mr. Tulipano is entitled to receive a performance-based bonus in the range of 0-49% of his base salary, with a target bonus of 30%, if certain performance targets are met, pursuant to his employment agreement.
- (5) Pursuant to the terms of a letter agreement that we entered into with Mr. Hamilton upon his resignation, we agreed to pay him a performance-based bonus equal to \$55,000 based upon the achievement of certain performance targets.
- (6) Dr. Mermelstein is entitled to receive a performance-based bonus of up to 89% of his base salary if certain performance targets are met.
- (7) Mr. Bernstein is entitled to receive a performance-based bonus of up to 30% of his base salary if certain performance targets are met, pursuant to his term sheet with us.
- (8) Mr. Bernstein's term as Secretary, General Counsel and Chief Intellectual Property Counsel commenced in April 2006.
- (9) Reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 computed in accordance with SFAS 123R, and thus may include amounts from awards granted in and prior to 2006. A discussion of the methods used to calculate these values may be found in footnote 10, which is in Part II, item 8 of this report.
- (10) Reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 computed in accordance with SFAS 123R for the modification of previously granted options.

## Grants of Plan-Based Awards

The following table sets forth certain information with respect to grants of plan-based awards for the year ended December 31, 2006 to the Named Executive Officers.

### GRANTS OF PLAN-BASED AWARDS

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of	All Other Option Awards: Number of Securities	Exercise or Base Price	Grant Date Fair Value of Stock
		Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (#)	Target (#) (1)	Maximum (\$)	Stock or Units (#)	Underlying Options (#)	of Option Awards (\$ / Sh)	and Option Awards (\$)
Daniel B. Carr, M.D.	3/8/06	—	—	—	—	125,000	—	—	—	\$ 4.05	\$340,000
Stephen J. Tulipano	5/1/06	—	—	—	—	150,000	—	—	—	\$ 3.70	\$373,500
Douglas A. Hamilton	3/8/06	—	—	—	—	75,000(2)	—	—	—	\$ 4.05	\$204,000
Fred H. Mermelstein	3/8/06	—	—	—	—	75,000	—	—	—	\$ 4.05	\$204,000
David B. Bernstein	4/10/06	—	—	—	—	150,000	—	—	—	\$ 3.50	\$352,500

(1) The options vest in three annual installments, beginning one year following the grant date.

(2) Mr. Hamilton was granted options to purchase up to 75,000 shares of common stock in March 2006. However, he forfeited all of these unvested options upon his resignation in May 2006.

### Discussion of Summary Compensation and Grants of Plan-Based Awards Tables

Our executive compensation policies and practices, pursuant to which the compensation set forth in the Summary Compensation Table and the Grants of Plan Based Awards Table was paid or awarded, are described above under "Compensation Discussion and Analysis." A summary of certain material terms of our compensation plans and arrangements is set forth below.

#### Employment Agreements

Pursuant to his employment agreement dated as of July 7, 2004, effective as of September 7, 2004, Dr. Carr was appointed our Chief Medical Officer and he became our Chief Executive Officer as of July 1, 2005. The employment agreement is for a term of three years, unless earlier terminated. Dr. Carr is receiving an initial annual base salary of \$350,000, plus a guaranteed bonus of \$50,000 payable within 30 days of the first anniversary of the effective date of the agreement, plus certain incentive compensation at the discretion of the board of directors, if certain performance targets are met, of up to \$320,000 or options for 200,000 shares of common stock. In addition, upon commencement of employment, Dr. Carr was granted an option to purchase 916,570 shares of common stock at an exercise price of \$1.96 per share, as adjusted for the merger, vesting in three equal installments commencing upon the first anniversary of the agreement. See "Payments Upon Termination or Change-in-Control" below for a discussion of payments due to Dr. Carr upon the termination of his employment or a change-in-control of our company.

Effective as of May 1, 2006, Stephen J. Tulipano became our Chief Financial Officer pursuant to an Employment Agreement, dated as of April 8, 2006. The employment term is two years and he is receiving an annual base salary of \$200,000 and is entitled to a discretionary performance-based bonus for the 2006 calendar year in the range of 0-49% of his base salary with a target bonus of 30% as determined in our sole discretion. As a hiring bonus, Mr. Tulipano was granted options to purchase 150,000 shares of common stock at an exercise price of \$3.70 per share, vesting in three equal annual installments commencing upon the first anniversary of the grant.

Effective as of April 2006, David Bernstein became our Secretary, General Counsel and Chief IP Counsel pursuant to a Term Sheet. The Term Sheet provides for a three year renewal term of employment, at an annual base salary of \$210,000, with an annual performance bonus of up to 30% of base salary in cash and annual performance options for up to 75,000 shares of common stock. Upon hiring, Mr. Bernstein

was granted options for the purchase of 150,000 shares of common stock at an exercise price of \$3.50 per share; vesting in three equal installments commencing on the first anniversary of the grant.

### Stock Option Plan

In February 2001, the Board of Directors and stockholders of IDDS approved the adoption of the 2000 Omnibus Stock Incentive Plan (the "IDDS Plan"). The IDDS Plan, as amended, provided for the issuance of 4,200,000 shares of IDDS common stock to be awarded to employees, consultants, directors and other individuals who render services to IDDS (collectively, "Awardees"). Awards include options, restricted shares, bonus shares, stock appreciation rights and performance shares (the "Awards"). The IDDS Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined. The IDDS Plan includes an automatic option grant program for non-employee directors, under which option grants will automatically be made at periodic intervals to non-employee board members to purchase shares of common stock as defined. The IDDS Plan provides for a Committee of the Board of Directors (the "Committee") to grant Awards to Awardees and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the Awards, including acceleration of the vesting of an Award at any time. All options granted under the IDDS Plan are intended to be non-qualified ("NQO") unless specified by the Committee to be incentive stock options ("ISO"), as defined by the Internal Revenue Code. NQO's may be granted to employees, consultants or other individuals at an exercise price equal to, below or above the fair value of the common stock on the date of grant. ISO's may only be granted to employees and may not be granted at exercise prices below fair value of the common stock on the date of grant (110% of fair value for employees who own 10% or more of the company). The period during which an option may be exercised may not exceed ten years from the date of grant (five years for grants of ISO's to employees who own 10% or more of the company). Under the IDDS Plan, for a period of one year following the termination of an Awardee's employment or active involvement, we have the right, should certain contingent events occur, to repurchase any or all shares of common stock acquired upon exercise of an Award held by the Awardee at a purchase price defined by the IDDS Plan. The IDDS Plan will terminate at the earliest of (i) its termination by the Committee, (ii) February 4, 2011 or (iii) the date on which all of the shares of common stock available for issuance under the IDDS Plan have been issued and all restrictions on such shares have lapsed. Awards granted before termination of the IDDS Plan will continue under the Plan until exercised, cancelled or expired.

Immediately prior to and as a condition of the Reverse Merger, we adopted the Intrac 2004 Omnibus Stock Incentive Plan (the "2004 Plan") covering the grant of stock options, restricted stock and other employee awards, subject to stockholder ratification. The terms of the 2004 Plan are substantially the same as the terms of the IDDS Plan. The 2004 Plan authorizes awards of up to 5,000,000 shares of common stock. Upon the closing of the Reverse Merger, the outstanding options under the IDDS Plan were exchanged for options under the 2004 Plan with the number of option shares and the exercise prices adjusted to reflect the merger exchange ratio (see Note 1). At the annual Meeting of Shareholders on September 7, 2005, our shareholders adopted the 2004 Plan.

Upon the closing of the Migratory Merger, the Javelin 2005 Omnibus Stock Incentive Plan (the "2005 Plan") became effective and the outstanding options under the 2004 Plan were exchanged for similar options under the 2005 Plan. The terms of the 2005 Plan are substantially the same as the 2004 Plan. The 2005 Plan shall continue in effect until the earlier of its termination by the Committee or the date on which all of the shares of common stock available for issuance thereunder have been issued and all restrictions on such shares under the terms of the 2005 Plan and the agreements evidencing awards have lapsed. On July 20, 2006, our shareholders approved an amendment to the 2005 Plan to increase the number of shares of common stock underlying the awards thereunder to 7,500,000 shares.

As of March 1, 2007, under the 2005 Plan, options for the purchase of an aggregate of 6,247,826 shares of our common stock were outstanding at exercise prices ranging from \$1.50 to \$5.40 per share. In addition, as of such date, there were outstanding options not granted under any plan for an aggregate of 1,184,058 shares of common stock at an exercise price of \$3.87 per share. There were 1,252,174 options remaining to be granted under the 2005 Plan.

## Outstanding Equity Awards

The following table sets forth certain information with respect to outstanding equity awards at December 31, 2006 with respect to the Named Executive Officers.

### OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Daniel B. Carr, M.D.	611,047	305,523	—	\$ 1.96	9/7/14	—	—	—	—
	4,167	8,333	—	\$ 2.70	4/12/15	—	—	—	—
	—	125,000	—	\$ 4.05	3/8/16	—	—	—	—
Stephen J. Tulipano	—	150,000	—	\$ 3.70	5/1/16	—	—	—	—
Douglas A. Hamilton	155,228	—	—	\$ 3.87	11/14/10	—	—	—	—
	152,762	—	—	\$ 1.50	11/12/07	—	—	—	—
	50,921	—	—	\$ 1.96	11/12/07	—	—	—	—
	75,000	—	—	\$ 2.70	11/12/07	—	—	—	—
	25,000	—	—	\$ 2.70	11/12/07	—	—	—	—
Fred H. Mermelstein, PhD.	103,485	—	—	\$ 3.87	11/14/10	—	—	—	—
	51,742	—	—	\$ 5.36	2/24/12	—	—	—	—
	50,921	—	—	\$ 3.87	9/18/12	—	—	—	—
	254,603	—	—	\$ 1.50	8/22/13	—	—	—	—
	127,301	—	—	\$ 1.96	12/15/13	—	—	—	—
	41,667	83,333	—	\$ 2.70	4/12/15	—	—	—	—
	75,000	—	—	\$ 2.70	4/12/15	—	—	—	—
—	75,000	—	\$ 4.05	3/8/16	—	—	—	—	
David B. Bernstein	—	150,000	—	\$ 3.50	4/10/16	—	—	—	—

#### Options Exercised and Stock Vested

None of our Named Executive Officers exercised any stock options during the 2006 fiscal year.

#### Pension Benefits

None of our Named Executive Officers or former executive officers are covered by a pension plan or other similar benefit plan that provides for payments or other benefits at, following, or in connection with retirement.

#### Nonqualified Deferred Compensation

None of our Named Executive Officers or former executive officers are covered by a defined contribution or other plan that provides for the deferral of compensation on a basis that is not tax-qualified.

## Payments Upon Termination or Change-in-Control

### *Daniel B. Carr, M.D.*

*Death or Disability.* Pursuant to the terms of his employment agreement, if Dr. Carr's employment is terminated as a result of his death or disability, Dr. Carr or Dr. Carr's estate, as applicable, would receive his base salary and any accrued but unpaid bonus and expense reimbursement amounts through the date of his death or the date on which the disability occurs. All stock options that are scheduled to vest by the end of the calendar year in which such termination occurs would be accelerated and become vested as of the date of his disability or death, and all stock options that have not vested (or been deemed pursuant to the immediately preceding sentence to have vested) as of the date of his disability or death shall be deemed to have expired as of such date.

*Cause.* If Dr. Carr's employment is terminated for cause, he would be entitled to his base salary and expense reimbursement through the date of termination, and he shall have no further entitlement to any other compensation or benefits. All stock options that have not vested as of the date of termination shall be deemed to have expired as of such date and any stock options that have vested as of the date of Dr. Carr's termination for cause would remain exercisable for a period of 90 days following the date of such termination.

*Change of Control.* If Dr. Carr's employment is terminated upon the occurrence of a change of control or within six months thereafter, we would be obligated to: (i) continue to pay his salary for a period of six months following such termination; (ii) pay any accrued and unpaid bonus; and (iii) pay expense reimbursement amounts through the date of termination. Also, all stock options that have not vested as of the date of such termination would be accelerated and deemed to have vested as of such termination date. Assuming that the change of control occurred on December 31, 2006, we would have paid to Dr. Carr \$175,000 of base salary and \$180,000 of accrued and unpaid bonus. The value of his accelerated options pursuant to SFAS 123R would have been \$665,000.

*Without Cause or for Good Reason.* If Dr. Carr's employment is terminated without cause, or by Dr. Carr for good reason, then we would be obligated to: (i) continue to pay his base salary for a period of 12 months from the date of such termination; (ii) pay the bonus he would have earned had he been employed for six months from the date on which such termination occurs; and (iii) pay any expense reimbursement amounts owed through the date of termination. All stock options that are scheduled to vest in the contract year of the date of such termination shall be accelerated and deemed to have vested as of the termination date. All stock options that have not vested (or deemed to have vested pursuant to the preceding sentence) shall be deemed expired, null and void. Any stock options that have vested as of the date of Dr. Carr's termination shall remain exercisable for a period as outlined in our omnibus stock option program. Assuming that the change of control occurred on December 31, 2006, we would have paid to Dr. Carr \$350,000 of base salary and \$180,000 of accrued and unpaid bonus. The value of his accelerated options pursuant to SFAS 123R would have been \$665,000.

*Employee Covenants.* In his employment agreement, Dr. Carr agreed to keep confidential and not disclose any confidential or proprietary information owned by, or received by or on behalf of, us or any of our affiliates, during the term of the agreement or at any time thereafter. He also agreed to return such confidential and proprietary information to us immediately in the event of any termination of employment.

Dr. Carr also agreed, during the term of the agreement and for a period of nine (9) months thereafter, to not in any manner enter into or engage in any business that is engaged in any business directly competitive with our business anywhere in the world, with limited exceptions. This non-competition covenant is not applicable if Dr. Carr is terminated by us without cause, or if he terminates the agreement for good reason.

Moreover, Dr. Carr agreed, during the term of the agreement and for a period of 12 months thereafter, to not, directly or indirectly, without our prior written consent: (i) solicit or induce any employee of us or any of our affiliates to leave such employment; or hire for any purpose any employee of us or any affiliate or any employee who has left such employment within one year of the termination of such employee's employment with us or any such affiliate or at any time in violation of such employee's non-competition agreement with us or any such affiliate; or (ii) solicit or accept employment or be retained by any person who, at any time during the term of the agreement, was an agent, client or customer of us or any of our affiliates where his position will be related to our business or the business of any such affiliate; or (iii) solicit or accept the business of any agent, client or customer of us or any of our affiliates with respect to products or services that compete directly with the products or services provided or supplied by us or any of our affiliates. This non-competition covenant is not applicable if Dr. Carr is terminated by us without cause, or if he terminates the agreement for good reason.

### *David B. Bernstein*

Pursuant to his Term Sheet for Employment, if Mr. Bernstein is terminated without cause, he shall be entitled to receive three (3) months' salary, which amount equaled \$52,500 as of December 31, 2006.

### *Douglas A. Hamilton*

Mr. Hamilton resigned as our Chief Financial Officer effective May 1, 2006, and as our Chief Operating Officer, Principal Financial Officer and Principal Accounting Officer effective May 12, 2006. In connection with his resignation, Mr. Hamilton entered into a letter agreement

with us dated July 7, 2006, which letter agreement was amended on July 24, 2006. Pursuant to the letter agreement, Mr. Hamilton was permitted to exercise all or any portion of his 458,911 vested options until November 12, 2007; provided, however, that the foregoing restriction does not apply to the 155,228 options granted to him pursuant to the option agreement dated September 7, 2005, which shall expire no earlier than November 14, 2010. The dollar value of the modification of the options pursuant to SFAS 123R was \$277,004. We also paid Mr. Hamilton a prorated bonus for 2006 equal to \$55,000, agreed to reimburse him up to \$3,500 for reasonable legal fees associated with the negotiation of the letter agreement, and agreed to pay his COBRA insurance premium through June 2007 (provided that he is not eligible for coverage under health benefits sponsored by any subsequent employer prior to that date). Mr. Hamilton agreed in the letter agreement to maintain the confidentiality of our proprietary information, and each party provided the other with a mutual release.

### ***2005 Omnibus Stock Incentive Plan***

***Corporate Transactions.*** Pursuant to the 2005 Plan, in the event that we approve a plan of complete liquidation or dissolution of our company, all options will terminate immediately prior to the consummation of such liquidation or dissolution. In the event that we approve an agreement for the sale of all or substantially all of our assets or a merger, consolidation or similar transaction in which we will not be the surviving entity or will survive as a wholly-owned subsidiary of another entity (each, a "Corporate Transaction"), the option shall be assumed or an equivalent option shall be substituted by such successor entity or a parent or subsidiary of such successor entity, unless the Board determines, in its sole discretion and in lieu of such assumption or substitution, to take one of the following two options: (i) fifteen (15) days prior to the scheduled consummation of such Corporate Transaction, all options shall become immediately vested and exercisable and shall remain exercisable for a period of fifteen days, or (ii) cancel any outstanding options and pay or deliver, or cause to be paid or delivered, to the holder thereof an amount in cash or securities having a value (as determined by the Board in its sole, good faith discretion) equal to the product of the number of shares subject to the option multiplied by the amount, if any, by which (A) the formula or fixed price per share paid to holders of shares pursuant to such Corporate Transaction exceeds (B) the option price applicable to such shares. With respect to establishment of an exercise window, (i) any exercise of an option during such fifteen-day period shall be conditioned upon the consummation of the contemplated Corporate Transaction and shall be effective only immediately before the consummation of such Corporate Transaction and (ii) upon consummation of such Corporate Transaction, the 2005 Plan and all outstanding but unexercised options shall terminate.

***Termination of Employment.*** If a grantee's employment or service is terminated for cause, any unexercised option shall terminate effective immediately upon such termination of employment or service. Except as otherwise provided by the Committee in the award agreement, if a grantee's employment or service terminates on account of death, then any unexercised option, to the extent exercisable on the date of such termination of employment or service, may be exercised, in whole or in part, within the first twelve (12) months after such termination of employment or service (but only during the option term) by (A) his or her personal representative or by the person to whom the option is transferred by will or the applicable laws of descent and distribution, (B) the grantee's designated beneficiary, or (C) a permitted transferee; and, to the extent that any such option was not exercisable on the date of such termination of employment or service, it will immediately terminate.

Except as otherwise provided by the Committee in the award agreement, if a grantee's employment or service terminates on account of disability, then any unexercised option, to the extent exercisable on the date of such termination of employment, may be exercised in whole or in part, within the first twelve (12) months after such termination of employment or service (but only during the option term) by the grantee, or by (A) his or her personal representative or by the person to whom the option is transferred by will or the applicable laws of descent and distribution, (B) the grantee's designated beneficiary or (C) a permitted transferee; and, to the extent that any such option was not exercisable on the date of such termination of employment, it will immediately terminate.

The degree, if any, to which any awards shall vest upon a change of control or a termination of employment or service in connection with a change of control shall be specified by the Committee in the applicable award agreement.

Except as otherwise provided by the Committee in the award agreement, if a grantee's employment or service terminates for any reason other than for cause, death, disability or pursuant to a change of control, then any unexercised option, to the extent exercisable immediately before the grantee's termination of employment or service, may be exercised in whole or in part, not later than three (3) months after such termination of employment or service (but only during the option term); and, to the extent that any such option was not exercisable on the date of such termination of employment or service, it will immediately terminate.

## DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)(4)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Douglas G. Watson (1)	\$24,500	—	\$132,561	—	—	—	\$157,061
Jackie M. Clegg	\$20,250	—	\$ 97,574	—	—	—	\$117,824
Martin J. Driscoll	\$ 9,500	—	\$ 57,348	—	—	—	\$ 66,848
Neil W. Flanzraich	\$10,250	—	\$ 57,348	—	—	—	\$ 67,598
Georg Nebgen	\$ 3,500	—	\$ 7,968	—	—	—	\$ 11,468
Peter M. Kash (2)	\$ 7,500	—	\$100,770	—	—	\$103,307 (5)	\$211,577
William P. Peters (3)	\$ 4,000	—	\$ 61,776	—	—	\$ 55,530 (6)	\$121,306

(1) As of December 31, 2006, each director had the following number of options outstanding: Mr. Watson – 236,565; Ms. Clegg – 175,921; Mr. Driscoll – 50,000; Mr. Flanzraich – 50,000; Mr. Nebgen – 50,000; Mr. Kash – 252,835; and Mr. Peters – 75,260.

(2) Mr. Kash resigned as a director as of December 8, 2006, at which time 48,425 unvested options were accelerated to vest on December 8, 2006, and 26,575 unvested options were forfeited. Upon his resignation, Mr. Kash executed a consulting agreement pursuant to which he agreed to provide consulting services to us until December 8, 2007 for a monthly fee of \$5,000. Mr. Kash's options are exercisable for a period of 18 months following the expiration or termination of the consulting agreement.

(3) Mr. Peters resigned as a director as of June 9, 2006, at which time all of his unvested options were forfeited, and the expiration date for all of his vested options was extended to December 8, 2007.

(4) Reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 computed in accordance with SFAS 123R, and thus may include amounts from awards granted in and prior to 2006. A discussion of the methods used to calculate these values may be found in footnote 10, Part II, item 8 of this report.

(5) Reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 computed in accordance with SFAS 123R for modification of options upon termination.

(6) Reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 computed in accordance with SFAS 123R for the modification of options upon termination.

### Director Compensation

We compensate the non-employee members of our Board for serving as a Board member up to \$2,500 per meeting for each meeting attended in person (\$1,000 for each meeting attended telephonically) and through the grant of stock options on an annual basis and a per meeting basis, including committee meetings. We also compensate non-employee directors for serving as committee members up to \$1,250 for each committee meeting attended in person and \$500 for each committee meeting attended telephonically.

Effective as of March 2006, our option policy is an Initial Option Award of options to purchase up to 50,000 shares of common stock to each non-employee director upon becoming a director vesting after one year. We also granted to our non-employee directors in the first quarter of the 2006 fiscal year a Basic Option Award of options to purchase up to 75,000 shares of common stock, which options vest one-third a year beginning one year after the grant date, and which cover service during the 2005-2007 fiscal years. In the first quarter of the 2009 fiscal year, we contemplate again granting a Basic Option Award of options to purchase up to 75,000 shares of common stock to our non-employee directors, which options will vest one-third a year beginning one year after the grant date, and which will cover service during the 2008-2010 fiscal years. Any non-employee director who is appointed following the grant of the Basic Option Award will be eligible for a pro-rated option award in the first quarter of the fiscal year following such non-employee director's appointment.

We also grant to our Chairman of the Board on an annual basis options to purchase up to 20,000 shares of common stock, to each committee member on an annual basis options to purchase up to 5,000 shares of common stock, to the chair of the Audit Committee on an annual basis options to purchase up to an additional 10,000 shares of common stock, and to the chair of the Compensation Committee and the Corporate Governance and Nominating Committee on an annual basis options to purchase up to an additional 5,000 shares of common stock. These options would vest one year following the grant date, and will have a term of ten years. The exercise price for all options granted to our directors would be the fair market value one the grant date.

If a non-employee director shall depart from the Board as a result of death or disability, all unvested options shall be accelerated to vest fully on the departure date, and be exercisable for a period of eighteen (18) months from the date of departure from the Board.

If a non-employee director shall depart from the Board voluntarily, options granted in the Initial Option Award shall be accelerated to be fully vested (if they are not already fully vested), all unvested options granted in the Basic Option Award shall be accelerated to be fully vested on a prorated basis for years actually served, all options granted for committee service shall be accelerated to be fully vested on a prorated basis for years actually served, and the vested options shall be exercisable for a period of eighteen (18) months from the date of resignation from the Board.

If a non-employee Director shall depart from the Board for cause, there shall be no acceleration of unvested options, and all unvested options shall terminate immediately upon the departure date. Vested options shall be exercisable for twelve (12) months.

#### **REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS**

The following report has been submitted by the Compensation Committee of the Board of Directors:

The Compensation Committee of the Board of Directors has reviewed and discussed our Compensation Discussion and Analysis with management. Based on this review and discussion, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in our annual report on Form 10-K for the fiscal year ended December 31, 2006, as filed with the SEC.

The foregoing report was submitted by the Compensation Committee of the Board and shall not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A promulgated by the SEC or Section 18 of the Securities Exchange Act of 1934.

Douglas G. Watson, Chair  
Jackie M. Clegg

## Compensation Committee Interlocks and Insider Participation

The Compensation Committee is currently composed of Mr. Watson, Chairman, and Ms. Clegg. Peter M. Kash served as a member of the Compensation Committee until his resignation on December 8, 2006. Neither Mr. Watson, Ms. Clegg nor Mr. Kash was an employee of our company during the 2006 fiscal year, or an officer of our company at any time in the past. No executive officer of our company serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our Board of Directors or Compensation Committee.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of the close of business on March 1, 2007 for (i) each person known by us to beneficially own more than 5% of our voting securities, (ii) each executive officer, (iii) each of our directors, and (iv) all of our executive officers and directors as a group.

Name and Address of Beneficial Owner (2)	Shares Beneficially Owned (1)	
	Number	Percent
Wexford Capital LLC (3) 411 West Putnam Avenue, Suite 125 Greenwich, CT 06930	5,012,642	12.34%
Lindsay A. Rosenwald (4) c/o Paramount BioCapital Investments, LLC 787 Seventh Avenue, 48th Floor New York, NY 10019	4,356,847	10.78%
NGN Capital, LLC (5) 369 Lexington Avenue, 17th Floor New York, NY 10017	3,266,667	8.05%
Fred H. Mermelstein (6)	1,326,202	3.22%
Georg Nebgen (7)	3,266,667	8.05%
Daniel B. Carr (8)	665,048	1.62%
Douglas G. Watson (9)	191,565	*
Jackie M. Clegg (10)	125,921	*
David B. Bernstein (11)	51,000	*
Stephen J. Tulipano (12)	- 0 -	*
Martin J. Driscoll (13)	- 0 -	*
Neil W. Flanzraich (13)	200,000	*
All officers and directors as a group (14)	5,826,403	13.73%

\* Beneficial ownership of less than 1% is omitted.

(1) The number of shares beneficially owned is determined under SEC rules, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power, and also any shares which the individual has the right to acquire within 60 days of March 1, 2007, through the exercise or conversion of any stock option, convertible security, warrant or other right (a "Presently Exercisable" security). Including those shares in the tables does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares.

- (2) Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of common stock listed as owned by that person or entity. Unless otherwise indicated, the address of each of the following persons is 125 CambridgePark Drive, Cambridge, MA 02140.
- (3) Includes (i) 2,568,198 shares owned of record by Wexford Spectrum Investors LLC and 111,111 shares obtainable upon exercise of Presently Exercisable Warrants and (ii) 2,222,222 shares owned of record by Theta Investors LLC and 111,111 shares obtainable upon exercise of Presently Exercisable Warrants, as reported on Schedule 13G/A, filed on February 7, 2006.
- (4) Includes (i) an aggregate of 1,672,673 shares with sole voting and dispositive power; (ii) 386,610 shares owned by Horizon Biomedical Ventures, LLC, of which Mr. Rosenwald is the managing member; and (iii) 1,981,064 shares owned by Mr. Rosenwald's wife for the benefit of his minor children, as reported on a Form 4 dated December 28, 2006. Mr. Rosenwald disclaims beneficial ownership of the shares held by his wife and by Horizon, except to the extent of his pecuniary interest therein, if any.
- (5) Includes (i) 1,805,689 shares owned of record by NGN Biomed Opportunity I, L.P., (ii) 1,305,422 shares owned of record by NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG, and (iii) 155,556 shares obtainable upon exercise of Presently Exercisable warrants. In their Schedule 13D, filed November 17, 2005, each of these persons expressly disclaimed membership in a "group" or beneficial ownership of any shares of common stock except for shares held of record.
- (6) Includes 771,386 shares obtainable upon exercise of Presently Exercisable options. Excludes 161,666 shares obtainable upon exercise of options not Presently Exercisable.
- (7) Includes: (i) 1,805,689 shares, and 90,285 shares obtainable upon exercise of Presently Exercisable warrants, owned of record by NGN Biomed Opportunity I, L.P. and (ii) 1,305,422 shares, and 65,271 shares obtainable upon exercise of Presently Exercisable warrants, owned of record by NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG, and excludes 76,644 shares obtainable upon exercise of options not Presently Exercisable, as reported on a Form 3 dated December 8, 2006, a Form 4 dated December 8, 2006 and a Form 4 dated January 3, 2007. Dr. Nebgen is a managing member of NGN Capital LLC ("NGN Capital"), which is the sole general partner of NGN Biomed I, L.P. ("NGN GP") and the managing limited partner of NGN Biomed Opportunity I GmbH & Co. Beteiligungs KG ("NGN Biomed I GMBH"). NGN GP is the sole general partner of NGN Biomed Opportunity I, L.P. Under the operating agreement for NGN Capital, Dr. Nebgen is deemed to hold the reported securities for the benefit of NGN Capital. NGN Capital may, therefore, be deemed the indirect beneficial owner of the securities, and Dr. Nebgen may be deemed the indirect beneficial owner through his indirect interest in NGN Capital. Dr. Nebgen disclaims beneficial ownership of the securities except to the extent of his pecuniary interest therein, if any.
- (8) Includes 661,048 shares obtainable upon exercise of Presently Exercisable options. Excludes 488,022 shares obtainable upon exercise of options not Presently Exercisable.
- (9) Includes 186,565 shares obtainable upon exercise of Presently Exercisable options. Excludes 85,000 shares obtainable upon exercise of options not Presently Exercisable.
- (10) Includes 125,921 shares obtainable upon exercise of Presently Exercisable options. Excludes 65,000 shares obtainable upon exercise of options not Presently Exercisable.
- (11) Includes 50,000 shares obtainable upon exercise of Presently Exercisable options. Excludes 143,000 shares obtainable upon exercise of options not Presently Exercisable.
- (12) Excludes 195,000 shares obtainable upon exercise of options not Presently Exercisable.
- (13) Excludes 91,604 shares obtainable upon exercise of options not Presently Exercisable.
- (14) Includes all shares of the persons denoted in footnotes (6) through (13).

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

Peter M. Kash, who resigned as a director effective as of December 8, 2006, is a principal of Two River Group Holding LLC ("Two River"). As of December 8, 2006, we retained Mr. Kash as a consultant for a period of one year at a fee of \$60,000 to provide certain investment relations services. In April 2005, we had retained Two River to provide certain investment relations services. The retention was through December 31, 2005 and the fee was a grant of five-year warrants for the purchase of 20,000 shares of common stock at an exercise price of \$3.00 per share.

River Bank Securities, Inc., a subsidiary of Two River, was a co-placement agent in our November 2005 placement for which it received \$1,151,992 in placement fees, placement warrants for the purchase of 512,000 shares of common stock exercisable at \$2.48 per share for five years, and reimbursement of its expenses.

We have entered into, or intend to enter into, indemnification agreements with each of our current directors. These agreements will require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors.

## Approval for Related Party Transactions

Although we have not adopted a formal policy relating to the approval of proposed transactions that we may enter into with any of our executive officers, directors and principal stockholders, including their immediate family members and affiliates, our Corporate Governance and Nominating Committee, all of the members of which are independent, reviews the terms of any and all such proposed material related party transactions. The results of this review are then communicated to the entire Board of Directors, which has the ultimate authority as to whether or not we enter into such transactions. We will not enter into any material related party transaction without the prior consent of our Nominating and Corporate Governance Committee and our Board of Directors. In approving or rejecting the proposed related party transaction, our Corporate Governance and Nominating Committee and our Board of Directors shall consider the relevant facts and circumstances available and deemed relevant to them, including, but not limited to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products, and, if applicable, the impact on a director's independence. We shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our Corporate Governance and Nominating Committee and our Board of Directors determine in the good faith exercise of their discretion.

## Director Independence

See the information set forth in the section titled "Corporate Governance—Board Composition" in Part III, Item 10 of this Annual Report.

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

For each of the two fiscal years ended December 31, 2006, the fees to our independent registered public accounting firm for services they rendered to us were as set forth below. A portion of the audit fees for 2006 and 2005 were paid in 2007 and 2006, respectively.

*Audit Fees.* The aggregate fees billed for professional services rendered in connection with (i) the audit of our annual financial statements, (ii) the review of the financial statements included in our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, (iii) consents and comfort letters issued in connection with equity offerings and (iv) services provided in connection with statutory and regulatory filings or engagements were \$377,169 for the fiscal year ended December 31, 2006 (of which \$207,169 was billed by PricewaterhouseCoopers, LLP ("PwC"), and \$170,000 was billed by McGladrey & Pullen, LLP ("McGladrey") and \$319,000 for the fiscal year ended December 31, 2005 (all of which was billed by "PwC").

*Audit-Related Fees.* We did not incur any audit-related fees for the fiscal years ended December 31, 2006 and December 31, 2005.

*Tax Fees.* We did not incur any tax fees for the fiscal years ended December 31, 2006 and December 31, 2005.

*All Other Fees.* We did not incur any other fees for the fiscal years ended December 31, 2006 and December 31, 2005.

As disclosed in the Current Report on Form 8-K filed with the SEC on October 13, 2006, we dismissed PwC as our independent registered public accounting firm, and retained McGladrey, on October 6, 2006.

## Pre-Approval Policies and Procedures

Rules adopted by the SEC in order to implement the requirements of the Sarbanes-Oxley Act of 2002 require public company audit committees to pre-approve audit and non-audit services. The Audit Committee has pre-approved the provision of audit and non-audit services by each independent registered public accounting firm for 2006 in accordance with its pre-approval policy. The pre-approval policy requires management to submit annually for approval to the Audit Committee a plan describing the scope of work and anticipated cost associated with each category of service. At each regular Audit Committee meeting, management reports on services performed by our independent registered public accounting firm and the fees paid or accrued through the end of the quarter preceding the meeting are discussed with management and representatives of our independent registered public accounting firm.

We have considered and determined that the provision of the non-audit services provided by our independent registered public accounting firms is compatible with maintaining each such firm's independence.

**PART IV.**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

**(a)(1)(2) Financial Statements and Financial Statement Schedule.**

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

**(a)(3) Exhibits.**

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

## SIGNATURES

Pursuant to the requirements of the 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 the 15th day of March 2007.

JAVELIN PHARMACEUTICALS, INC.

By: /s/ Daniel B. Carr  
Name: Daniel B. Carr, M.D.  
Title: Chief Executive Officer and  
Chief Medical Officer

## POWER OF ATTORNEY

Each director and/or officer of the registrant whose signature appears below hereby appoints Daniel B. Carr, M.D. or Fred H. Mermelstein, Ph.D. as his attorney-in-fact to sign in his name and behalf, in any and all capacities stated below, and to file with the Securities and Exchange Commission, any and all amendments, to this Annual Report of Form 10-K.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Daniel B. Carr</u> Daniel B. Carr	Chief Executive Officer, Chief Medical Officer and Director (Principal Executive Officer)	March 15, 2007
<u>/s/ Stephen J. Tulipano</u> Stephen J. Tulipano	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2007
<u>/s/ Fred H. Mermelstein</u> Fred H. Mermelstein	President and Director	March 15, 2007
<u>/s/ Douglas G. Watson</u> Douglas G. Watson	Chairman of the Board and Director	March 15, 2007
<u>/s/ Jackie M. Clegg</u> Jackie M. Clegg	Director	March 15, 2007
<u>/s/ Martin J. Driscoll</u> Martin J. Driscoll	Director	March 15, 2007
<u>/s/ Neil W. Flanzraich</u> Neil W. Flanzraich	Director	March 15, 2007
<u>/s/ Georg Nebgen</u> Georg Nebgen	Director	March 15, 2007

## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
2.1	Agreement and Plan of Merger dated December 6, 2004 among Intrac, Inc. ("Intrac"), Intrac Merger Sub Inc. ("Intrac Sub"), and Innovative Drug Delivery Systems, Inc. ("IDDS") (filed as Exhibit 2.1 to our Form 8-K filed December 10, 2004 (the "December 10 Form 8-K"), and incorporated herein by reference).
2.2	Agreement and Plan of Merger, dated as of July 27, 2005, between Intrac and the Company (filed as Appendix B to the Intrac Proxy Statement, dated August 1, 2005, and incorporated herein by reference).
3.1	Certificate of Incorporation (filed as Exhibit 3.1 to our Form 8-K, filed September 9, 2005 (the "September 2005 Form 8-K"), and incorporated herein by reference).
3.2	Certificate of Amendment to Certificate of Incorporation (filed as Exhibit 3.1 to our Form 8-K filed July 25, 2006, and incorporated herein by reference).
3.3	Bylaws (filed as Exhibit 3.2 to the September 2005 Form 8-K, and incorporate herein by reference).
3.4	Certificate of Merger between the Company and Intrac Inc., filed on September 7, 2005 with the Secretary of State of the State of Delaware (filed as Exhibit 3.3 to the September 2005 Form 8-K, and incorporated herein by reference).
4.1	2004 Omnibus Stock Incentive Plan (filed as Exhibit 4.1 to the December 10 Form 8-K, and incorporated herein by reference).
4.2	Form of Common Stock Purchase Warrant, dated November 5, 2004, issued by IDDS as part of bridge financing (filed as Exhibit 4.3 to our Registration Statement on Form SB-2 filed January 20, 2005 (the "2005 Form SB 2"), and incorporated herein by reference).
4.3	Placement Agent Warrant Agreement, dated December 6, 2004, issued by IDDS (filed as Exhibit 4.4 to the 2005 Form SB-2, and incorporated herein by reference).
4.4	Form of Common Stock Purchase Warrant (filed as Exhibit 4.1 to our Form 8-K, filed November 10, 2005 (the "November 2005 Form 8-K"), and incorporated herein by reference).
4.5	Form of Placement Agent Warrants (filed as Exhibit 4.2 to the November 2005 Form 8-K, and incorporated herein by reference).
4.6	Common Stock Purchase Warrant, dated September 7, 2005, issued to Aurora Capital LLC (filed as Exhibit 4.6 to our Form 10-K for the fiscal year ended December 31, 2005 (the "2005 Form 10-K"), and incorporated herein by reference).
4.7.1	Common Stock Purchase Warrant, dated September 7, 2005, issued to The Investor Relations Group, Inc. (filed as Exhibit 4.7.1 to the 2005 Form 10-K, and incorporated herein by reference).
4.7.2	Common Stock Purchase Warrant, dated September 30, 2005, issued to The Investor Relations Group, Inc. (filed as Exhibit 4.7.2 to the 2005 Form 10-K, and incorporated herein by reference).
4.8	Common Stock Purchase Warrant, dated September 7, 2005, issued to Two River Group Holding, LLC (filed as Exhibit 4.8 to the 2005 Form 10-K, and incorporated herein by reference).
4.9	Amended and Restated 2005 Omnibus Stock Incentive Plan.
10.1.1	Form of Subscription Agreement for December 2004 IDDS Placement (filed as Exhibit 10.2 to the December 10 Form 8-K, and incorporated herein by reference).
10.1.2	Form of Registration Rights Agreement dated as of December 6, 2004 between IDDS and each purchaser in the December 2004 IDDS Placement (filed as Exhibit 10.3 to the December 10 Form 8-K, and incorporated herein by reference).
10.2	License Agreement effective as of December 14, 2001 among Farmarc N.A.N.V., Farmarc Netherlands B.V., Shimoda Biotech (Proprietary) Ltd. and IDDS (filed as Exhibit 10.11 to IDDS Registration Statement on Form S-1 (No. 333-76190)(the "IDDS Form S-1"), and incorporated herein by reference).

<b>Exhibit No.</b>	<b>Description</b>
10.3.1	License Agreement dated as of August 25, 2000 among West Pharmaceutical Services, Inc., West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd. and IDDS (filed as Exhibit 10.4 to the IDDS Form S-1, and incorporated herein by reference).
10.3.2	Amendment, dated February 8, 2005 to West Pharmaceutical Services Agreement (filed as Exhibit 10.3.2 to the 2004 Form 10KSB, and incorporated herein by reference).
10.4	License Agreement effective as of February 25, 1998 between Dr. Stuart Weg and IDDS (as successor in interest to Pain Management, Inc.) (filed as Exhibit 10.2 to the IDDS Form S-1, and incorporated herein by reference).
10.5	Employment Agreement, dated as of September 7, 2004, between IDDS and Daniel B. Carr (filed as Exhibit 10.5 to the December 10 Form 8-K, and incorporated herein by reference).
10.6.1	Securities Purchase Agreement dated as of November 4, 2004 among the Purchasers therein and IDDS (filed as Exhibit 10.6.1 to the 2005 Form SB-2, and incorporated herein by reference).
10.6.2	Form of 10% Senior Secured Debenture, dated November 4, 2004, in the aggregate principal amount of \$1,000,000 issued by IDDS (filed as Exhibit 10.6.2 to the 2005 Form SB-2, and incorporated herein by reference).
10.7.1	Securities Purchase Agreement, dated as of November 3, 2005 among the investors therein and the Company (filed as Exhibit 10.1 to the November 2005 Form 8-K, and incorporated herein by reference).
10.7.2	Registration Rights Agreement, dated as of November 7, 2005, among the Holders therein and the Company (filed as Exhibit 10.2 to the November 2005 Form 8-K, and incorporated herein by reference).
10.8	Employment Agreement, dated as of April 8, 2006, between the Company and Stephen J. Tulipano (filed as Exhibit 10.1 to our Form 8-K, filed on April 26, 2006, and incorporated herein by reference).
10.9	Term Sheet for Employment of David B. Bernstein, dated as of March 2, 2006 (filed as Exhibit 10.2 to our Form 8-K filed on April 26, 2006, and incorporated herein by reference).
10.10*	Commercial Supply Agreement, dated February 15, 2007, between the Company and Precision Pharma Services, Inc.
16.1	Letter from Paritz & Company, P.A., dated December 13, 2004 (filed as Exhibit 16.1 to our Form 8-K filed for an event of December 13, 2004, and incorporated herein by reference).
21*	List of Subsidiaries.
23.1*	Consent of McGladrey & Pullen, LLP, independent registered public accounting firm.
23.2*	Consent of PricewaterhouseCoopers, LLP, independent registered public accounting firm.
24*	Power of Attorney (on signature page).
31.1*	Certification of our Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of our Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of our Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of our Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*	Filed herewith

# Corporate Information

## Board of Directors

**Douglas G. Watson**  
*CEO, Pittenger Glen Associates and former  
President & CEO, Novartis Corporation*

**Fred H. Marmelstein, PhD**  
*President & Founder, Javelin Pharmaceuticals, Inc.*

**Jackie M. Clegg**  
*CEO, Clegg International Consultants LLC, former Vice Chair  
and First VP of the Export-Import Bank of the United States*

**Daniel B. Carr, MD**  
*CEO/CMO, Javelin Pharmaceuticals, Inc.*

**Nell Flanzrath**  
*Former Vice Chairman & President of MAX Corporation*

**Martin Driscoll**  
*Principal, MID Consulting LLC, former SVP, Marketing  
and Sales at Rahant Pharmaceuticals*

**Georg Nebgen, PhD**  
*Managing General Partner & Co-founder, NGN Capital,  
former Executive at Schering-Plough Corporation*

## Officers

**Daniel B. Carr, MD**  
*Chief Executive Officer & Chief Medical Officer*

**Fred H. Marmelstein, PhD**  
*President & Founder*

**Stephen J. Tullipano, CPA, MBA**  
*Chief Financial Officer*

**David B. Bernstein, Esq.**  
*General Counsel & Chief Intellectual Property Counsel*

**Curtis Wright IV, MD, MPH**  
*Executive Vice President, Risk Management & Regulatory Affairs*

**Michael Moshman, MBA**  
*Vice President, Chemistry, Manufacturing & Controls*

**Michael T. Sheddler, MBA**  
*Vice President, Business Development*

**Mark Matthews**  
*Vice President, Commercial Affairs*

**Frederick E. Pierce, II**  
*Vice President, Investor Relations*

## Corporate Counsel

**Pryor Cashman LLP**  
410 Park Avenue  
New York, NY 10022

## Independent Registered Public Accounting Firm

**McGladrey & Pullen, LLP**  
7 New England Executive Park, Suite 320  
Burlington, MA 01808

## Registrar & Transfer Agent

**American Stock Transfer and Trust**  
59 Maiden Lane  
New York, NY 10038  
Toll-free number for shareholder questions: 800-937-5449  
International: 718-921-8200

## Company Investor Contact

**Frederick E. Pierce, II**  
*Vice President, Investor Relations*  
Javelin Pharmaceuticals, Inc.  
125 CambridgePark Drive  
Cambridge, MA 02140  
Phone: 617-349-4500  
Fax: 617-349-4505  
fr@javelinpharmaceuticals.com

## Common Stock Information

Javelin's stock is traded on the American Stock Exchange under the symbol: JAV

## Annual Meeting

The Javelin Pharmaceuticals Annual Meeting of Stockholders will be held:  
Tuesday, June 26, 2007 at 9:30am  
The American Stock Exchange  
86 Trinity Place  
New York, NY

## Financial & Other Company Information

Our annual report on Form 10-K for the fiscal year ended December 31, 2006, is available on our website at [www.javelinpharmaceuticals.com](http://www.javelinpharmaceuticals.com) under the Investors Information section or at [www.sec.gov](http://www.sec.gov). In addition, other SEC filings, news releases and Company information are available on our corporate website. The headquarters of Javelin Pharmaceuticals is located in Cambridge, MA. The company has additional offices in Lake Success, NY and Cambridge, United Kingdom.



125 CambridgePark Drive  
Cambridge, MA 02140  
(617) 349-4500

[www.javelinpharmaceuticals.com](http://www.javelinpharmaceuticals.com)

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