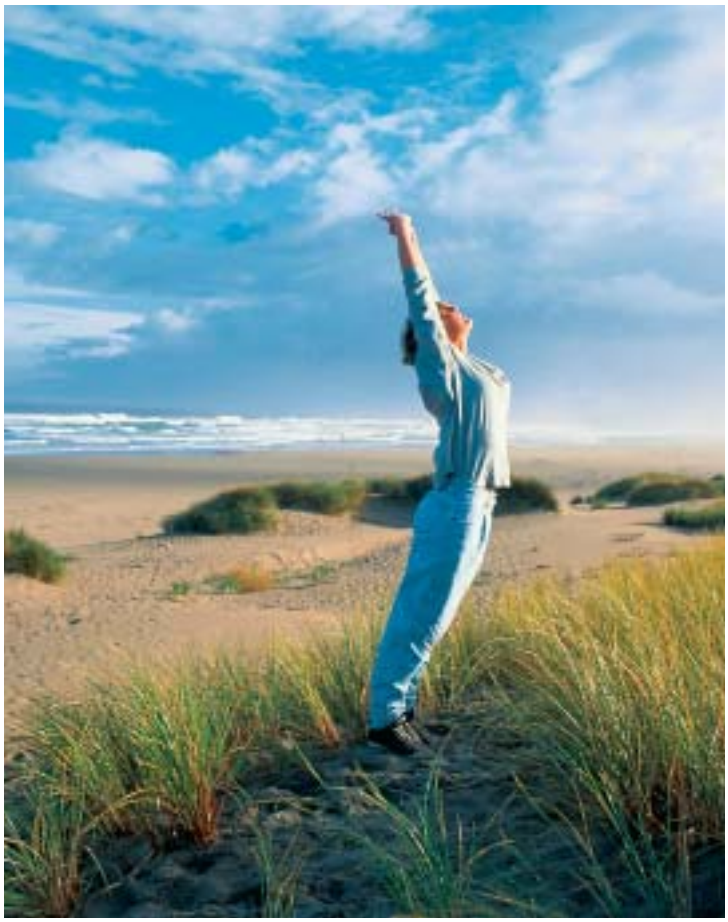
Pharmaceutical Systems for Chronic Disease



DURECT™

DURECT CORPORATION 2001 annual report

DURECT CORPORATION is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the right amount at the right time. DURECT's lead product in development, the CHRONOGESIC™ (sufentanil) Pain Therapy System, a 3-month product for the treatment of chronic pain, completed a pilot phase III study in November 2001. DURECT owns three biodegradable drug delivery platform technologies, including the SABER™ Delivery System (a versatile depot injectable particularly useful for protein delivery), the MICRODUR™ Biodegradable Microparticles (microsphere injectable system) and the DURIN™ Biodegradable Implant (drug-loaded polymer implant system).

To Our Stockholders

2001 was an exceptional year for DURECT. We made substantial progress in the development of our CHRONOGESIC™ (sufentanil) Pain Therapy System, a product that continuously delivers pain medication for three months to treat patients suffering from moderate to severe chronic pain. We announced positive results from a Phase II trial for the CHRONOGESIC™ product and completed a pilot Phase III study during the year. The credit for our accomplishments last year goes to our employees. Their experience, dedication and hard work have been responsible for our success.

OUR TECHNOLOGIES During the past year, we also acquired Southern BioSystems, Inc. and added an experienced team of specialists and patented technologies in the field of depot injectables, implants and biodegradable polymers. Through our internal development programs and with the acquisition of Southern BioSystems, we have increased the breadth and depth of our technology platforms.

Our research programs and broad technology base have allowed us to make significant progress in four therapeutic franchise areas, including pain management, central nervous system disorders, cardiovascular diseases and biotechnology-based therapies.

There are a host of product candidates that we are currently evaluating. We are focusing our development efforts on a selected number of products, some of which we will commercialize ourselves and others which we expect to partner with pharmaceutical and other life sciences companies. To that end, we are conducting studies to eliminate the key hurdles for each of these programs in order to establish realistic plans for product development. We are currently in discussions with potential corporate partners for over half of our products we have in development.

BREADTH OF EXPERIENCE DURECT is a 4-year-old company, but the experience of our employees, who are industry leaders in this field, goes back over 30 years. We have been able to recruit an accomplished management team that has participated in bringing literally billions of dollars worth of products to the market. Our vision for product development is to leverage the experience of our employees, and combine known drugs (both in terms of efficacy and side effect profile) with proven systems to minimize product development risk and speed time to market. This strategy reduces much of the development risk that is inherent in traditional pharmaceutical product discovery.

We believe we have the experience and the corporate strategy in place to become a leading specialty pharmaceutical company. We plan to aggressively advance our product candidates and search for new business opportunities with partners that will increase value for our stockholders and improve the quality of life for patients with chronic diseases and conditions throughout the world.

Jim Brown, D.V.M.
PRESIDENT, CHIEF EXECUTIVE OFFICER AND CO-FOUNDER

Felix Theeuwes, D.Sc.
CHAIRMAN, CHIEF SCIENTIFIC OFFICER AND CO-FOUNDER

Tom Schreck
CHIEF FINANCIAL OFFICER AND CO-FOUNDER

Improving Patients' Quality of Life

OUR MISSION is to restore the well being of patients through developing and marketing innovative pharmaceutical systems that treat chronic debilitating diseases and enable biotechnology-based products.

Moving Patients from Dependence to Independence

CHRONOGESIC™ (Sufentanil) Pain Therapy System

PAIN FRANCHISE Chronic pain, defined as pain lasting 6 months or longer, is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. Chronic nonmalignant pain affects as many as 34 million Americans annually. In addition, the National Cancer Institute estimates that 8.4 million Americans alive today have a history of cancer. About 1.2 million new cancer cases were expected to be diagnosed in 2000, and about 50%-70% of cancer patients experience chronic pain during the course of the disease. Sales of opioids for the treatment of moderate to severe chronic malignant and nonmalignant pain exceed $2 billion.

With our lead product, the CHRONOGESIC™ (sufentanil) Pain Therapy System, we intend to target patients with opioid responsive chronic pain that results from a variety of causes. The CHRONOGESIC™ product delivers sufentanil continuously within the therapeutic window, at physician prescribed doses for three months of pain therapy. Sufentanil is an opioid that is currently used in hospitals as an analgesic.

The CHRONOGESIC™ product addresses the potential problems of peaks (too much medication) and troughs (too little medication) associated with pills and patches. This product will provide an alternative to current therapies for the treatment of chronic pain and may provide for less risk of potential misuse, abuse and diversion than traditional pills or patches. The ability of the CHRONOGESIC™ product to provide controlled dosing will allow physicians to prescribe and safely administer to patients, a clinically necessary opioid for moderate to severe chronic pain for three months.

In 2001, we made significant progress in the development of the CHRONOGESIC™ product. We completed a Phase II trial in which patients preferred the CHRONOGESIC™ product by a two-to-one margin versus their previous pain medication. Patients not only reported a reduction in side effects when compared with their previous medications, but also reported improved quality of life, such as improved sleep patterns. In 2001 we also completed a pilot Phase III study which confirmed our conversion strategy for transitioning patients from other opioid medications to the CHRONOGESIC™ product.

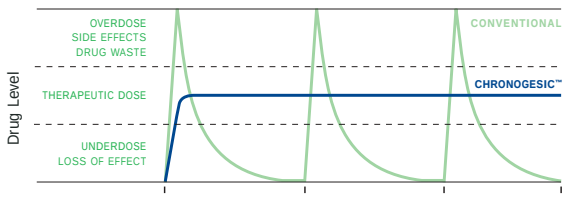
The CHRONOGESIC™ product's potential to improve the quality of life of patients suffering from chronic pain will be evaluated in pivotal Phase III clinical trials starting in 2002. The primary objectives of our pivotal Phase III program are to demonstrate that patients can be safely transitioned from a variety of existing opioids, such as pills and patches, to the CHRONOGESIC™ product, as well as to demonstrate that the CHRONOGESIC™ product provides safe and effective pain relief at least equivalent to the patient's existing pain therapy.

The CHRONOGESIC™ product uses a proven drug delivery technology called the DUROS® system developed at ALZA, a Johnson & Johnson company.

Potential Advantages for Patients:

- More consistent pain control than previous regimens
- Increased activity tolerance
- Improved sleep
- Patients can forget about their condition

CHRONOGESIC™ vs. Conventional Drug Administration:



Delivering the Right Drug, to the Right Site, in the Right Amount at the Right Time

THE DUROS® TECHNOLOGY PLATFORM is an implantable drug-dispensing osmotic pump. The system is shaped as a small rod with titanium housing, which can be as small as a matchstick, designed to release medication. We have licensed this proven and patented technology for specified fields of use from ALZA Corporation. The potential of the DUROS® technology as a platform for providing drug therapy was demonstrated by the FDA's approval of ALZA's VIADUR product (leoprolide acetate implant) for the palliative treatment of prostate cancer.

The DUROS® pump operates like a miniature syringe loaded with a drug inside the drug reservoir. Through osmosis, water from the body is slowly drawn through a semipermeable membrane into the pump by salt residing in the engine compartment. This water fills the pump engine compartment, which slowly and continuously pushes a piston, dispensing the correct amount of drug out the drug reservoir and into the body. The osmotic engine does not require batteries, switches or other electromechanical parts in order to operate. The amount of drug delivered by the system is regulated by this osmotic mechanism and by the concentration of the drug in the drug reservoir.

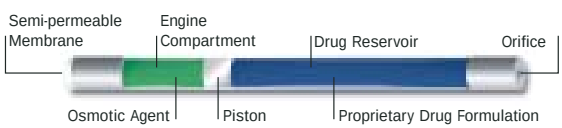
The DUROS® system can be used for therapies requiring systemic or site-specific administration of a drug. To deliver drugs systemically, the DUROS® system is placed just under the skin of the upper arm in an outpatient procedure. This procedure is completed in just 3 to 5 minutes using local anesthetic.

To deliver a drug to a specific site, we are developing proprietary miniaturized catheter technology. The catheter can be attached to the DUROS® system to direct the flow of a drug to the target organ, tissue or synthetic medical structure, such as a vascular graft. Site-specific delivery enables a therapeutic concentration of a drug to be administered to the desired target without exposing the entire body to a similar concentration. The precision, size and performance of the DUROS® system will allow for continuous site-specific delivery to a variety of precise locations within the body.

COMPOUNDS FOR USE WITH THE DUROS® TECHNOLOGY The DUROS® technology has the potential to provide more flexibility than competitive technologies regarding the types of drugs that can be administered, including proteins, peptides and genes because the drug dispensing mechanism is independent from the drug substance.

Our unique drug delivery capabilities may accelerate the development and commercialization of many biotech compounds that may not be an effective and safe therapy when administered using conventional methods. When used with our proprietary catheters, the DUROS® system can deliver large biotech molecules to their intended site of action to increase efficacy and reduce side effects.

DUROS® Technology:



Potential Advantages for Prescribers:

- Physician controlled dosing
- Constant, stable drug delivery, no peaks and troughs
- Long duration between treatments, fewer visits and prescriptions
- Less risk of diversion/abuse/misuse

Product Pipeline

TECHNOLOGIES Our pharmaceutical systems combine technology innovations from the medical device and drug delivery industries with proprietary pharmaceutical and biotechnology drug formulations. These capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biotechnology molecules such as proteins, peptides and genes. We are currently developing products in the following franchises:

PAIN / CARDIOVASCULAR / CENTRAL NERVOUS SYSTEM / BIOTECHNOLOGY

PRODUCT / CHRONOGESIC™
INDICATION / Chronic Pain
DRUG / Sufentanil
SYSTEM / DUROS®
FRANCHISE / Pain

FOCUS / SABER™ Injection
INDICATION / Post Operative Pain
DRUG / Local Anesthetic
SYSTEM / SABER™
FRANCHISE / Pain

PRODUCT / IntraEAR® Micro-Catheter
APPLICATION / Inner Ear Disorders

PHASE III

COMMERCIAL PRODUCTS

PRODUCT / ALZET® Osmotic Pumps
APPLICATION / Pre-Clinical Research

PRODUCT / LACTEL® Biodegradable Polymers
APPLICATION / Components for depot and implant technology

DURECT's Product Franchises

PAIN FRANCHISE / LOCAL POST-OPERATIVE PAIN In the United States, 25 million hospital surgeries occur annually. The current standard of care for post surgical pain includes oral opiate and non-opiate analgesics, transdermal opiate patches, and muscle relaxants. While oral analgesics may control post surgical pain, they commonly cause side effects such as drowsiness, constipation, and cognitive impairment. Post surgical pain can be treated with local anesthetics, however the usefulness of these medications is limited by their short duration of action.

We are developing a sustained-release formulation of a local anesthetic using our SABER™ Delivery System for the treatment of post surgical pain. This analgesic will be injected by the physician at the time of surgery and placed adjacent to the surgical site. By delivering effective amounts of a potent analgesic to the location from which the pain originates, local pain control can be achieved with minimal exposure to the remainder of the body, and hence minimal side effects. The duration of local delivery coincides with the typical timeline by which post surgical pain resolves in most patients. We are currently conducting preclinical studies on this product.

PAIN FRANCHISE / SPINAL DELIVERY PAIN Infusion of opiates into the spinal fluid has become accepted medical therapy in patients who find high dose oral or transdermal opioids ineffective or who experience side effects that make systemic therapy unacceptable. Although there are many implantable infusion pumps on the market today, these pumps tend to be relatively large and require a costly surgical procedure to implant. A need exists for a minimally invasive, spinal infusion device that has improved cost benefit for patients with chronic pain.

Our strategy is to develop an infusion system that can deliver an opioid into the spinal fluid via a catheter. This product will be considerably smaller and less invasive than currently available spinal infusion pumps, allowing for implantation on an outpatient basis. We are currently conducting pre-clinical studies on this product.

CARDIOVASCULAR FRANCHISE About 58 million Americans, roughly 25% of the population, are currently living with some form of cardiovascular disease. Ischemic heart disease, one of the major forms of cardiovascular disease, is the leading cause of death worldwide. Existing treatments for ischemia, or insufficient blood flow to the heart muscle, include cardiovascular bypass, angioplasty and the use of cardiovascular stents and similar medical devices. While effective, these treatments are invasive and in roughly 40% of patients, ischemia returns within 2 years. There is a need for less invasive and more long lasting treatments for ischemic heart disease.

In collaboration with the University of Maastricht in The Netherlands, we are working to develop methods for treating ischemic heart disease and other chronic cardiovascular diseases through continuous pericardial delivery. Our research in animal models suggests that ischemic heart disease may be treated by continuously delivering an angiogenic factor to spur new blood vessel growth, thereby increasing blood flow, and restoring function to the diseased heart.

CENTRAL NERVOUS SYSTEM FRANCHISE Millions of people suffer from chronic diseases and disorders of the central nervous system (CNS), including brain and spinal cord tumors, psychosis, epilepsy, Parkinson's disease, and multiple sclerosis. It is expected that 180,000 new brain tumors will be diagnosed in the United States in 2001. Current treatments for CNS tumors include radiation, resection and chemotherapy. Treatment success rates vary by tumor type, but are generally low and the risk of side effects or disability is high. It is generally recognized that improvements in treating primary metastatic brain tumors are needed, particularly for those which are inoperable.

We currently have a collaboration with the Johns Hopkins University, Department of Neurology/Neurosurgery, exploring the feasibility of treating tumors of the brain stem by site-specific delivery of a chemotherapeutic agent directly to the tumor via a DUROS® system attached to a catheter. The program is currently in preclinical development studies in primates.

It is estimated that about 2.5 million patients are afflicted with schizophrenia in the United States, the incidence is about 250 million worldwide. Adherence to prescribed drug regimens is recognized as a significant treatment obstacle in the schizophrenic population. Although it is estimated that 50% of patients in the U.S. are either untreated or under treated, the aggregated sales of antipyschotic medications in 2000 exceeded $5.7 billion. Opportunities exist to apply our pharmaceutical systems for treatment of these and other CNS disorders.

We are developing our DUROS® platform technology in combination with various catheter systems for targeted delivery of drugs to treat select CNS disorders. We are also developing our bioerodible platform technologies for systemic and targeted delivery of select CNS disorders.

BIOTECHNOLOGY FRANCHISE Drugs developed out of the biotechnology industry are today mainly administered by repeated, frequent injection. The desirability of dosage forms that can reliably administer proteins for long periods of time is readily acknowledged. We are currently researching various products utilizing our biodegradable platform technologies in combination with protein molecules having known efficacy against major diseases with a goal to develop products that require less frequent administration than products currently available on the market.

DUROS® Catheter:

Platform Technologies with Wide Applications

SABER™ The SABER™ system is a patented controlled-release technology that can be formulated for systemic or local administration of active agents via the parenteral (i.e. non-oral) or oral route. We are researching and developing a variety of controlled-release products based on the SABER™ technology. These include injectable controlled-release products for systemic and local delivery and oral products.

Our SABER™ system has the potential to provide the basis for the development of a state-of-the-art biodegradable, controlled-release depot injectable. The SABER™ system uses a high-viscosity base component, such as sucrose acetate isobutyrate (SAIB), to provide controlled release of active ingredients. When the high viscosity SAIB is formulated with drug, a biocompatible diluent and other additives, the resulting formulation is liquid enough to inject easily with standard syringes and needles. After injection of a SABER™ formulation, the solvent diffuses away, leaving a viscous deposit.

The SABER™ system has the potential to successfully deliver therapeutic levels of a wide spectrum of drugs from 1 day to 3 months from a single subcutaneous injection. Based on research and development work to date, our SABER™ technology has shown the following advantages:

- Peptide/Protein Delivery – The chemical nature of the SABER™ system tends to stabilize proteins and peptides. For this reasons, we believe that the SABER™ system is well suited as a platform for biotechnology therapeutics based on proteins and peptides.
- Less Burst – Animal studies have shown that injectables based on SABER™ can be associated with less post-injection burst than is typically associated with other controlled-release technologies.
- High Drug Concentration - Drug concentration in a SABER™ formulation can be as high as 30%, considerably greater than is typical with other commercially available controlled-release technologies.
- Ease of Administration – Prior to administration, SABER™ formulations are fairly liquid and therefore can be administered through small needles. Additionally, because of the higher drug concentration of SABER™ formulations, less volume is required to be injected. Small injection volumes and more liquid solutions result in easier, less painful administration.
- Strong Patent Protection - The SABER™ system and various applications of this technology to pharmaceutics and drug delivery are covered by United States and foreign patents.
- Ease of Manufacture - Compared to microspheres and other polymer-based controlled-release injectable systems, SABER™ is readily manufacturable at low cost.

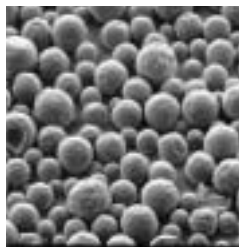
The SABER™ system has the potential to deliver drugs from 1 day to 3 months from a single injection. A diluent is added to the SABER™ formulation prior to injection to provide ease of administration. After injection of the SABER™ formulation, the diluent diffuses away, leaving a viscous deposit.

SABER™ ORAL DOSAGE FORMS The SABER™ technology may be used as the basis of controlled-release oral technology, which can transform short-acting oral dosage forms into controlled-release oral products. In March 2002 we entered into an agreement with Cardinal Health Pharmaceutical Technologies and Services Center, Inc. to explore the feasibility of producing long acting gel-cap products, using SABER™ technology as core formulations. R.P. Scherer Corporation, a subsidiary of Cardinal Health, is a leading developer and manufacturer of soft-gelatin capsules, rapid-dissolving tablets and other drug delivery systems.

THE DURIN™ BIODEGRADABLE IMPLANT TECHNOLOGY Our DURIN™ technology is a biodegradable implant that enables parenteral (i.e., non-oral) delivery of drugs from several weeks to six months or more. The DURIN™ technology can deliver a wide variety of drug compounds as well as small and large molecules. Our proprietary implant design allows for a variety of possible delivery profiles including constant rate delivery. Because DURIN™ implants are biodegradable, at the end of its delivery life, what remains of the DURIN™ implant is absorbed by the body. We are researching and developing products based on the DURIN™ technology for a variety of chronic disease applications.

THE MICRODUR™ BIODEGRADABLE MICROPARTICULATE TECHNOLOGY Our MICRODUR™ technology is a biodegradable microparticulate depot injectable. Within our subsidiary, Southern BioSystems, we have experience in microencapsulation of a broad spectrum of drugs using polymers and co-polymers of lactic and glycolic acid. In our MICRODUR™ process, both standard and proprietary polymers are used to entrap an active agent in solid matrices or capsules comprising particles generally between 10 and 125 microns in diameter. Through suitable choice of polymers and processing, sustained release from a few days to many months can be achieved. As with the DURIN™ technology, MICRODUR™ particles degrade fully in the body after the active agent is released. Our range of experience extends from manufacture of the polymer raw material to process and product development, scale up and cGMP manufacture.

BIRMINGHAM POLYMERS INC. (BPI) Is a wholly owned subsidiary of Southern BioSystems. BPI designs, develops and manufactures for pharmaceutical clients a wide range of standard and custom polymers under the LACTEL® tradename. These materials are used by Southern BioSystems and other BPI customers for a variety of controlled-release and medical-device applications, including several FDA-approved commercial products.



From Left to Right: the SABER™ Oral dosage form, the DURIN™ Biodegradable Implant Technology and the MICRODUR™ Biodegradable Microparticulate Technology (microscopic photograph).

Specialized Capabilities and an Experienced Management Team

CAPABILITIES OF DURECT DURECT is a development stage company based in Cupertino, California. Over 150 employees focus on developing therapies that offer improved outcomes for patients suffering from chronic diseases. Over 90 of these employees are focused in technical development functions of drug research, product engineering, formulation and development.

The DURECT manufacturing facility, located near our headquarters in Cupertino, is a fully integrated facility covering all aspects of the CHRONOGESIC™ product production, from raw material staging through packaging. Designed to meet initial requirements for market launch, the facility was constructed according to FDA requirements for cGMP operation.

The manufacturing facility occupies approximately 8,000 square feet of space within our laboratory and engineering building and consists of three types of areas: component preparation; component subassembly, and aseptic filling operations.

The Southern BioSystem facility in Birmingham, Alabama, manufactures biodegradable polymers for the pharmaceutical and medical device industries and develops controlled-release products for the Company and its customers based on our three proprietary delivery platforms.

DURECT also sells the ALZET® Osmotic Pumps for use in laboratory research and IntraEAR® catheters which are used by physicians to treat inner ear disorders.

SENIOR MANAGEMENT In order to build a successful pharmaceutical systems organization, a company must have the right people to accomplish its goals. Our management team has extensive and broad experience from the pharmaceutical, biotechnology and medical device industries. As far as tenure in industry, DURECT averages over 15 years of experience per person in senior management, with each member possessing extensive experience developing and successfully bringing products to the marketplace.

< SOUTHERN BIOSYSTEMS EXECUTIVES

< DURECT SENIOR MANAGEMENT

PICTURED FROM LEFT TO RIGHT Timothy S. Nelson, Vice President of Business and Commercial Development, Jean I Liu, Vice President, Legal and General Counsel, Scott M. Wheelwright, Ph.D., Vice President of Manufacturing, Evelyn R. Robledo, Vice President of Quality Assurance and Compliance, Judy A. Magruder, Senior Vice President of Regulatory and Development, Randolph M. Johnson, Ph.D., Vice President of Preclinical Research and Director of Central Nervous System Programs, Edward M. Gillis, Vice President of Product Engineering, Tai Wah Chan, Ph.D., Vice President of Pharmaceutical Research and Development, Dennis M. Fisher, MD, Vice President of Medical Affairs and Medical Director, Su IL Yum, Vice President of Engineering. PICTURED SEPARATELY Arthur J. Tipton, Ph.D. Vice President and Chief Scientific Officer of Southern Biosystems, Inc., Wallace B. Smith, Ph.D., President of Southern Biosystems, Inc.

EXECUTIVE MANAGEMENT

James E. Brown, D.V.M.
President and Chief Executive Officer

Felix Theeuwes, D.Sc.
Chairman and Chief Scientific Officer

Thomas A. Schreck
Chief Financial Officer

BOARD OF DIRECTORS

Felix Theeuwes, D.Sc., Chairman

James E. Brown, D.V.M.

Thomas A. Schreck

James R. Butler

John L. Doyle

Armand P. Neukermans, Ph.D.

Matthew V. McPherron

Albert L. Zesiger

ADDITIONAL INFORMATION

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SENIOR MANAGEMENT

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Vice President of Pharmaceutical
Research and Development

Dennis M. Fisher, MD
Vice President of Medical Affairs
and Medical Director

Edward M. Gillis
Vice President of Product Engineering

Randolph M. Johnson, Ph.D.
Vice President of Preclinical
Research and Director of
Central Nervous System Programs

Jean I Liu
Vice President,
Legal and General Counsel

Timothy S. Nelson
Vice President of Business
and Commercial Development

Evelyn R. Robledo
Vice President of Quality Assurance
and Compliance

Scott M. Wheelwright, Ph.D.
Vice President of Manufacturing

Su IL Yum, Ph.D.
Vice President of Engineering

SOUTHERN BIOSYSTEMS, INC.

Wallace B. Smith, Ph.D.
President

Arthur J. Tipton, Ph.D.
Vice President
and Chief Scientific Officer

ANNUAL MEETING

The Company's annual meeting of stockholders will be held at 9:00 A.M. local time on June 5, 2002 at Company headquarters.

AUDITORS

Ernst & Young LLP
Palo Alto, CA

LEGAL COUNSEL

Venture Law Group
Menlo Park, CA

TRANSFER AGENT

EquiServe Trust Company, N.A.
150 Royall Street
Canton, MA 02021 USA
Phone (781) 575-3400

SEC FORM 10-K

A copy of the Company's annual report to the United States Securities and Exchange Commission on Form 10-K is available without charge upon written request to:
DURECT Corporation
Attn: Investor Relations
10240 Bubb Road
Cupertino, CA 95014

TRADEMARKS

The statements in this annual report regarding DURECT's products in development, product development plans, or expected product benefits or anticipated product markets, are forward-looking statements involving risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, DURECT's ability to develop, manufacture and commercialize its products, successfully complete clinical trials, and obtain product and manufacturing approvals from regulatory agencies, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in the company's quarterly and annual reports filed with the SEC, including Annual Report on Form 10K filed with the SEC on March 28, 2002 under the heading "Factors that may affect future results."

The CHRONOGESIC™ (sufentanil) Pain Therapy System is under development by DURECT and has not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

DESIGN: Artemis® Creative, Inc. www.artemis-creative.com

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