



DURECT Completes Construction of Commercial Manufacturing Facility

CUPERTINO, Calif., May 24 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX – news) today announced that it has completed construction of a commercial manufacturing facility that is expected to meet DURECT’s production needs for Phase III clinical batches, FDA registration batches and commercial launch of DUROS sufentanil. The facility is designed to use advanced procedures to enhance the DUROS manufacturing process, which should increase production capacity and allow pilot manufacturing for a number of additional products. The new facility will comprise approximately 8,000 sq. ft. and will be located at DURECT’s headquarters in Cupertino, California.

The facility is designed to house an aseptic clean-room space for aseptic filling and an advanced manufacturing process capable of supporting clean assembly, packaging and labeling. DURECT plans to manufacture Phase III clinical batches and FDA registration batches for DUROS sufentanil from this facility.

“We are pleased to reach this important milestone. Construction of this facility was completed on schedule, and we are proceeding with validating and qualifying this facility,” said Jim Brown, CEO of DURECT.

DURECT Corporation is pioneering the development and commercialization of pharmaceutical systems to deliver the right drug to the right site in the right amount at the right time. DURECT’s 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.

DURECT’s lead product in development, DUROS sufentanil, is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is a FDA approved opioid that is currently used in hospitals as an anesthetic. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. DUROS sufentanil is intended for patients whose chronic pain is stable, opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain exceed \$1 billion.

DURECT’s second product in development, DUROS hydromorphone, continuously delivers hydromorphone to the spine. DURECT also sells FDA cleared catheters for the delivery of fluids to the inner ear and manufactures and sells and distributes the ALZET® osmotic pump product for use in laboratory research.

Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation, researches, develops and manufactures controlled-release drug delivery products to help clients commercialize human and veterinary pharmaceuticals. Southern BioSystems has three drug-delivery platforms: the proprietary SABER(TM) delivery system, microspheres and drug-loaded implants. SABER(TM) is a biodegradable highly viscous liquid that can be formulated for oral, parenteral dermal or other routes of administration. Southern BioSystems has the capabilities to formulate microspheres for oral, parenteral, dermal or other routes of administration. Southern BioSystems also develops drug-loaded implants and, through its subsidiary Birmingham Polymers, also manufactures biodegradable polymers.

Founded in 1998, DURECT is headquartered in Cupertino, CA. The company’s World Wide Web site can be accessed at <http://www.durect.com>. The company’s World Wide Web site for ALZET osmotic pumps, IntraEAR and Southern BioSystems, Inc. can be accessed at <http://www.alzet.com>, <http://www.intraear.com> and <http://www.southernbiosystems.com>, respectively. To join DURECT’s email alert service, please register by selecting “Email Alerts” on the main Investor Relations web page at <http://www.durect.com>.

DUROS is a registered trademark of ALZA Corporation. SABER(TM) is a trademark of Southern BioSystems, Inc., a subsidiary of DURECT Corporation.

The statements in this press release regarding DURECT’s products in development, product development plans, or expected product benefits, 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, obtain product and manufacturing approvals from regulatory agencies, and validate and qualify a manufacturing facility, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in the company's S-1 registration statement, filed with the SEC on September 22, 2000, 424(b) prospectus filed with the SEC on September 28, 2000, Quarterly Report on Form 10Q for the quarter ended September 30, 2000 filed with the SEC on November 14, 2000 and Annual Report on Form 10K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001.

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