DURECT Corporation Announces Earnings and Reports Strong Progress on Its Business

CUPERTINO, Calif., Feb. 16 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2000 and reports strong progress in the company's business operations.

The company reiterated its accelerated progress in the Phase II clinical trials for DUROS sufentanil and announced that it expects to complete patient enrollment before the end of second quarter 2001, which is approximately two months ahead of its previous timelines. The company estimates that a number of physicians active in the Phase II trial will also enroll participants in the Phase III trial, with a number of potential patients already identified for treatment. During the first half of 2001, DURECT will begin discussions with a major pharmaceutical company for a U.S. and Canada distribution relationship and has already initiated conversations with potential marketing partners outside of the U.S.

DURECT has completed the development of a prototype clinical system for its second product in development, a DUROS-based pharmaceutical system for the delivery of hydromorphone to the spine for the treatment of end stage cancer pain. End-stage cancer pain is a market segment that is not served by commercially available implanted pumps today. The company's product is being developed to fit the clinical practice of the oncologist. DURECT has finalized the company's pharmaceutical formulation for the product and is beginning preparation of its IND filing with plans to move the product into the clinic in the second half of 2001.

DURECT also announced that the construction of its manufacturing facility is on schedule with most of the mechanical work complete. The new facility will comprise approximately 8,000 square feet and will be located at DURECT's headquarters in Cupertino, CA. DURECT has implemented a number of improved efficiencies and automated procedures to greatly enhance the DUROS manufacturing process. The Company believes the new DUROS manufacturing process is more streamlined and efficient and believes should increase production rates and clinical batch output. DURECT plans to manufacture Phase III clinical batches and FDA registration batches for DUROS sufentanil from the facility. The facility is designed to house a state-of-the-art aseptic cleanroom space, an advanced manufacturing process capable of supporting clean assembly and an automated aseptic filling operation. DURECT expects the facility to have sufficient manufacturing capacity to provide commercial quantities of the company's lead product, as well, the facility is planned to have a flexible, modular design to produce clinical supplies for future products under development by the company. DURECT expects to complete the construction of this facility in the first half of 2001 and validation by the second half of 2001.

DURECT continues to make progress on the research side in a number of other therapeutic areas and plans to move its third program into product development before the end of 2001.

On a pro forma basis, DURECT's net loss for the three months ended December 31, 1999 was $3.3 million, or 11 cents per share. For the year ended December 31, 2000, DURECT's net loss was $20.8 million, or $1.22 per share, compared to a net loss of $9.3 million, or $1.76 per share, for the year ended December 31, 1999. On a pro forma basis, the net loss for the year ended December 31, 2000 was $19.9 million, or 54 cents per share, compared to a net loss of $8.7 million, or 37 cents per share, for the year ended December 31, 1999.

The increase in net loss for 2000 compared to the net loss in 1999 was primarily due to, but not limited to, the company's preparation for and commencement of Phase II clinical trials for the company's lead product, DUROS sufentanil, for the treatment of chronic pain, completing the prototype design of the company's second product in development, DUROS hydromorphone for terminal cancer pain, and research activities aimed at broadening the technology base and identifying new product opportunities.

The Company also announced that its 2000 Annual Meeting of Stockholders has been scheduled for June 27, 2001.

"We are pleased with the company's progress over the past year. For the year 2000, we met our key company milestones, including commencement of Phase II clinical trials for our lead product, beginning construction on our commercial manufacturing facility, and completing a prototype design for our spinal delivery program for our second product, DUROS hydromorphone for end-stage cancer pain. We completed two financings, including an initial public offering of DURECT common stock, which together raised net proceeds of approximately $109 million," said James E. Brown, President and Chief Executive Officer of DURECT. "We are also very pleased at the progress that we have made in 2001 with our patient enrollment for our Phase II trial for DUROS sufentanil. The accelerated pace exceeds our expectations, and we expect this trial to complete ahead of the previously anticipated schedule."

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 initial portfolio of products combine the DUROS technology, a proven and patented drug delivery platform licensed for specified fields of use from ALZA Corporation, with drugs for which medical data on efficacy and safety are available.

DURECT's lead product in development, DUROS sufentanil, is for the treatment of chronic pain. DUROS sufentanil is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Annual sales of opioids for the treatment of chronic pain are in excess of $1 billion. DURECT's second product, DUROS hydromorphone, is a DUROS-based pharmaceutical system for the delivery of hydromorphone to the spine for the

treatment of end stage cancer pain. DURECT is also selling FDA cleared catheters for the delivery of fluids to the inner ear. DURECT also manufactures, sells and distributes the ALZET(R) osmotic pump product for use in laboratory research.

Founded in 1998, the Company is headquartered in Cupertino, CA. The Company's World Wide Web site can be accessed at http://www.www.durect.com. To join DURECT's email alert service, please register by selecting "Email Alerts" on the main Investor Relations web page at http://www.www.durect.com.

DUROS is a registered trademark of ALZA Corporation.

The statements in this press release regarding DURECT's products in development, product development plans, clinical trials, and 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, complete successful clinical trials, obtain product approvals from regulatory agencies, build a manufacturing facility, marketplace acceptance of DURECT's products and DURECT's ability to manage its growth and costs. 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 and its 424(b) prospectus filed with the SEC on September 28, 2000 and its Quarterly Report on Form 10Q for the quarter ended September 30, 2000 filed with the SEC on November 13, 2000.

For further information please contact:

DURECT Corporation

Schond L. Greenway Director, Investor Relations

Phone: (408) 777-1417

schond.greenway@durect.com
SOURCE DURECT Corporation

CONTACT: Schond L. Greenway Director, Investor Relations of DURECT Corporation, 408-777-1417, schond.greenway@durect.com/