DURECT Corporation Reports First Quarter 2002 Financial Results

CUPERTINO, Calif., Apr 24, 2002 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2002.

DURECT's net loss for the three months ended March 31, 2002 was \$9.7 million or 20 cents per share, compared to \$4.9 million or 11 cents per share for the same period in 2001. DURECT's results for the three months ended March 31, 2002 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$933,000, compared to \$1.2 million for the same period in 2001.

"DURECT has begun 2002 by continuing strong progress in our business," stated Dr. Jim Brown, CEO of DURECT. "To date, we have announced positive results from our pilot phase III trial for our lead product, the CHRONOGESIC(TM) (sufentanil) Pain Therapy System. In the trial, we successfully converted patients from the Duragesic(R) product to the CHRONOGESIC product without observing clinically-relevant side effects or adverse events. We are on track with our goal to initiate our pivotal Phase III trials mid-year for the CHRONOGESIC product."

"We had significant progress in our R&D efforts this quarter," stated Dr. Felix Theeuwes, Chairman and CSO of DURECT. "In March, we announced that we had entered into a collaboration with Cardinal Health to research and develop long acting oral gel-cap products using our SABER(TM) Delivery System. The use of our SABER core formulations in soft-gelatin capsules has the potential of expanding the soft-gelatin capsule business into the controlled-release markets. We also recently announced that we filed an investigational new drug application (IND) with the FDA to investigate the delivery of cromolyn sodium for the treatment of asthma and allergic rhinitis (seasonal allergies) utilizing one of the Company's proprietary biodegradable drug delivery platforms."

Research and development expenses were \$8.0 million in the three months ended March 31, 2002, compared to \$4.1 million for the same period in 2001. The increase was primarily attributable to expanded research and development activities, especially related to preparation for the company's pivotal Phase III clinical trials for its lead product, CHRONOGESIC. The increase was also attributable to continued investments in the research and development of other pharmaceutical systems and the hiring of additional research and development personnel.

Selling, general and administrative expenses were \$2.3 million in the three months ended March 31, 2002, compared to \$1.9 million for the same period in 2001. The increase was primarily due to the expansion of corporate infrastructure to support the growth in all areas of DURECT's business.

At March 31, 2002, DURECT had cash and investments of \$67.4 million, including \$3.4 million in restricted investments.

DURECT expects its net loss for the second quarter of 2002 to be in the range of

\$10.5 million to \$11.0 million or 22 to 23 cents per share. DURECT's estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately \$800,000 for the second quarter of 2002.

DURECT Corporation (www.www.durect.com) 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(TM) (sufentanil) Pain Therapy System, a 3-month product for the treatment of chronic pain, completed a pilot phase III study in December 2001. DURECT owns three proprietary drug delivery platform technologies, including the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system).

CHRONOGESIC(TM) is a trademark of DURECT Corporation. SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation. Other trademarks referred to belong to their respective owners.

The statements in this press release regarding DURECT's products in development, expected product benefits, product development plans, future clinical trials, potential product markets or projected future financial results are forward-looking statements involving risks and uncertainties that can 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 research, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, finance its activities and operations, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 filed with the SEC on March 28, 2002, under the heading "Factors that may affect future results," and other periodic reports filed with the SEC. CHRONOGESIC 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.

DURECT CORPORATION CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts)

	Three months ended March 31,	
	2002 (unaudited)	2001 (unaudited)
Revenue, net	\$1,624	\$1,399
Cost of goods sold (1)	779	611
Gross profit	845	788

Operating expenses:				
Research and development Research and development to	7,983	4,094		
related party Selling, general and	12	47		
administrative	2,323	1,878		
Amortization of intangible assets Stock-based compensation (1)	335 569	274 935		
Total operating expenses	11,222	7,228		
Loss from operations	(10,377)	(6,440)		
Other income (expense): Interest income Interest expense Net other income	711 (83) 628	1,584 (62) 1,522		
Net loss	\$(9,749)	\$(4,918)		
Net loss per share, basic and diluted	\$(0.20)	\$(0.11)		
Shares used in computing basic and diluted net loss per share	47,782	45,128		
(1) Stock-based compensation related to the following:				
Cost of goods sold Research and development Selling, general and administrative Total stock-based compensation	\$29 394 175 \$598	\$22 680 255 \$957		
DURECT CORPORATION CONDENSED CONSOLIDATED BALANCE SHEET (in thousands)				
	March 31, 2002 (unaudited)	December 31, 2001*		

Assets Current assets: Cash, cash equivalents and short-term investments \$55,285 \$55,204 Inventories and other current assets 4,407 5,007 Total current assets 59,692 60,211

Property and equipment, net Intangible assets, net Long-term investments and other non-	13,449 9,842	13,136 10,178
current assets	12,068	21,418
Total assets	\$95,051	\$104,943
Liabilities and stockholders' equity Current liabilities: Accounts payable and accrued		
liabilities Long-term obligations, current	\$4,660	\$5,065
portion	573	683
Total current liabilities	5,233	5,748
Long-term obligations, noncurrent		
portion	2,140	2,147
Stockholders' equity	87,678	97,048
Total liabilities and stockholders' equity	\$95,051	\$104,943
(*) Derived from audited financial statement	s.	

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