DURECT Corporation Reports Fourth Quarter 2001 and Year End Financial Results

CUPERTINO, Calif., Jan. 30 /PRNewswire-FirstCall/ —
DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2001.

The Company's net loss attributable to common stockholders for the three months ended December 31, 2001 was $10.1 million or 21 cents per share, compared to $4.9 million or 11 cents per share for the same period in 2000. DURECT's results for the three months ended December 31, 2001 include non-cash charges for the amortization of intangible assets and stock-based compensation of $1.3 million, compared to $1.4 million for the same period in 2000.

Excluding a one-time charge for acquired in-process research and development of $14.0 million, the Company's net loss attributable to common stockholders for the year ended December 31, 2001 was $30.9 million or 67 cents per share compared to $20.8 million or $1.22 per share for the same period in 2000. Including the charge for acquired in-process research and development, DURECT's net loss attributable to common stockholders for the year ended December 31, 2001 was $44.9 million or 97 cents per share. DURECT's results for the year ended December 31, 2001 also include non-cash charges for the amortization of intangible assets and stock-based compensation of $5.3 million, compared to $5.9 million for the same period in 2000.

"2001 was an exceptional year for DURECT," stated Jim Brown, President and CEO of DURECT. "We made substantial progress in the development of our lead product Chronogesic(TM). We completed Phase II trials in which we saw a two-to-one patient preference for Chronogesic(TM) versus their previous opioid pain medicine, and we completed a pilot Phase III study. During the past year, we also acquired Southern BioSystems, Inc. which vastly expanded our technology base. Our own internal development activities in combination with our broad technology base has allowed us to make significant progress in our research programs in the four therapeutic franchise areas we are targeting, including pain management, central nervous system disorders, cardiovascular diseases and biotechnology therapies."

The increases in net loss for the three months and twelve months ended December 31, 2001 as compared to the same periods in the prior year were primarily due to the expansion of development activities related to the Company's lead product, Chronogesic(TM), including clinical trial and related expenses, and the hiring of additional research and development personnel. To support its growth, the Company increased general and administrative and related expenses. The increase in net loss for the year ended December 31, 2001 compared to 2000 was also due to a one-time charge for acquired in-process research and development in connection with the acquisition of Southern BioSystems, Inc.

At December 31, 2001, the Company had cash and investments of $76.6 million, including $3.4 million in restricted investments.

The Company expects its net loss for the first quarter of 2002 will range

from $10.0 million to $10.5 million or 21 to 22 cents per share. The Company expects its net loss will range from $41.0 million to $43.0 million or 85 to 89 cents per share for the fiscal year 2002. The Company's estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately $3.0 million for the fiscal year 2002.

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 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 focuses on the treatment of chronic diseases including pain, CNS disorders, cardiovascular disease and cancer. DURECT holds an exclusive license from ALZA Corporation to develop and commercialize products in selected fields based on the DUROS(R) implant technology. Chronogesic(TM), a 3-month continuous infusion subcutaneous implant for the treatment of chronic pain, is the first product in this series and completed phase II testing in June 2001. DURECT also owns three proprietary erodible implant platform technologies, including SABER(TM) (a patented and versatile depot injectable useful for protein delivery), MICRODUR(TM) (microspheres injectable system) and DURIN(TM) (drug-loaded implant system). DURECT also commercializes ALZET(R) Osmotic Pumps for research animal use, IntraEAR(R) catheters which have been used by physicians to treat inner ear disorders and PLGA based biodegradable polymers.

Founded in 1998, DURECT 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.

NOTE: Chronogesic(TM), IntraEAR(R) and ALZET(R) are trademarks of DURECT Corporation. SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation. DUROS(R) is a trademark of ALZA Corporation.

The statements in this press release regarding DURECT's products in development, expected product benefits, product development plans, potential product markets or projected future financial results 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 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 Current Report on Form 8-K filed with the SEC on January 11, 2002, Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 filed with the SEC on November 13, 2001, and Annual Report on Form 10-K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001, under the heading "Factors that may affect future results." Chronogesic(TM) 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)

	Quarter ended December 31,		Year ended December 31,	
	2001	2000	2001	2000*
	(unaudited)		(unaudited)	
Revenue, net	$1,597	$973	$6,524	$3,155
Cost of goods sold (1)	850	685	3,398	1,941
Gross profit	747	288	3,126	1,214
Operating expenses:				
Research and development	7,882	4,028	24,472	12,669
Research and development to related party	7	40	98	666
Selling, general and administrative	2,441	1,504	8,779	4,874
Amortization of intangible assets	554	342	1,844	850
Acquired in-process research and development	--	--	14,030	--
Stock-based compensation (1)	701	1,046	3,305	4,978
Total operating expenses	11,585	6,960	52,528	24,037
Loss from operations	(10,838)	(6,672)	(49,402)	(22,823)
Other income (expense):				
Interest income	837	1,781	4,796	3,103
Interest expense	(85)	(43)	(322)	(131)
Net other income	752	1,738	4,474	2,972
Net Loss	(10,086)	(4,934)	(44,928)	(19,851)
Accretion of cumulative dividends on Series B convertible preferred stock	--	--	--	972
Net loss attributable to common stockholders	$(10,086)	$(4,934)	$(44,928)	$(20,823)
Net loss per common share, basic and diluted	$(0.21)	$(0.11)	$(0.97)	$(1.22)
Shares used in computing basic and diluted net loss per share	47,304	44,126	46,414	17,120

Pro forma net loss per share, basic and diluted (2)	$(0.54)
Shares used in computing pro forma net loss per share (2)	36,659

(1) Stock-based compensation related to the following:

Cost of goods sold	$29	$22	$146	$65
Research and development	438	741	2,235	3,426
Selling, general and administrative	263	305	1,070	1,552
Total stock-based compensation	$730	$1,068	$3,451	$5,043

(2) Reflects the pro forma conversion of preferred stock into common stock as of the beginning of the period.

- derived from audited financial statements.

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2001 (unaudited)	December 31, 2000*
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$55,204	$104,432
Inventories and other current assets	5,007	4,881
Total current assets	60,211	109,313
Property and equipment, net	13,136	4,472
Intangible assets, net	10,178	5,175
Long-term investments	21,418	1,652
Total assets	$104,943	$120,612
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$5,065	$3,846
Long-term obligations, current portion	683	407
Total current liabilities	5,748	4,253
Long-term obligations, noncurrent portion	2,147	1,105

Stockholders' equity	97,048	115,254
Total liabilities and stockholders' equity	$104,943	$120,612

- derived from audited financial statements.

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