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DURECT Corporation Reports Fourth Quarter 2000 and Year End Financial Results

CUPERTINO, Calif., Feb. 15 /PRNewswire/ ----

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2000.

The Company's net loss attributable to common stockholders for the three months ended December 31, 2000 was \$4.9 million or 11 cents per share, compared to a net loss of \$3.6 million, or 60 cents per share, for the three months ended December 31, 1999. 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. Concurrent with the company's initial public offering on September 28, 2000, all shares of preferred stock were converted into common stock. Pro forma calculations assume the conversion of all preferred stock, at the date of issuance, into common stock. DURECT's results include non-cash charges for the amortization of intangible assets and stock-based compensation of \$1.4 million and \$5.9 million for the fourth guarter and the year ended December 31, 2000, respectively and \$0.6 million and \$0.9 million for the same periods in 1999.

"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 8-10 weeks ahead of the previously anticipated schedule."

The increase in net loss for 2000 compared to the net loss in 1999 was primarily due to the company's preparation for and commencement of Phase II clinical trials for its lead product, DUROS sufentanil, for the treatment of chronic pain. The increases in operating expenses were primarily due to increases in research and development expenses, selling, general and administrative expenses and non-cash items including amortization and stock-based compensation. The increase in research and development expenses was attributable to activity related to DUROS sufentanil Phase II trials, increases in research and development personnel and related payroll, and increases in contract research and development. The increase in selling, general and administrative expenses was primarily due to an increase in general and administrative personnel and related expenses necessary to support



DURECT's growth.

At December 31, 2000, the Company had cash, cash equivalents, and investments of \$106.1 million, compared to \$18.9 million as of December 31, 1999. This increase was primarily due to the proceeds from the sale of common stock from DURECT's initial public offering, which closed on October 3rd, 2000.

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

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 30, 2000 filed with the SEC on November 13, 2000.

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There will be a conference call at 4:30 p.m. EST today to discuss DURECT's fourth quarter and year-end financial results as well as the outlook for 2001. This call will be broadcast live over the Internet at http://www.www.durect.com under "Investor Relations." If you are unable to participate during the live webcast, the call will be archived at:

http://www.www.durect.com/wt/frame.php?page_name=investor Minimum Requirements to listen to broadcast: The RealPlayer software, downloadable free from http://www.real.com/products/player/index.html, and at least a 14.4Kbps connection to the Internet. If you experience problems listening to the broadcast, send an email to webmaster@vdat.com.)

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

	2000	er 31, 1999	Year e Decemb 2000 naudited)		
Revenue, net Cost of goods sold (1) Gross profit	\$973 685 288	\$86 39 47	\$3,155 1,941 1,214	\$86 39 47	
Operating expenses: Research and development Research and development	4,028	2,069	-	5,181	
to related party Selling, general and administrative Amortization of intangible	40 1,504	321 644	666 4,874	1,182 2,109	
assets Stock-based compensation	342	69	850	69	
(1) Total operating expenses	1,046 6,960	514 3,617	•	865 9,406	
Loss from operations	(6,672)	(3,570)	(22,823)	(9,359)	
Other income (expense): Interest income Interest expense Net other income	1,781 (43) 1,738	303 (7) 296	3,103 (131) 2,972	678 (27) 651	



Net Loss	(4,934)	(3,274)	(19,851)	(8,708)
Accretion of cumulative dividends on Series B convertible preferred stock		331	972	602
Net loss attributable to common stockholders	\$(4,934)	\$(3,605)	\$(20,823)	\$(9,310)
Net loss per common share, basic and diluted	\$(0.11)	\$(0.60)	\$(1.22)	\$(1.76)
Shares used in computing basic and diluted net loss per share	44,126	6,000	17,120	5,291
Pro forma net loss per share, basic and diluted		\$(0.11)	\$(0.54)	\$(0.37)
Shares used in computing pro forma net loss per share		29,928	36,659	23,771
(1) Stock-based compensation related to the following:				
Cost of goods sold Research and development Selling, general and administrative	\$22 741	\$ 316	\$65 3,426	\$ 485
	305 \$1,068	198 \$514		380 \$865

*derived from audited financial statements.

DURECT CORPORATION CONDENSED BALANCE SHEETS (in thousands)

	December 31, 2000 (unaudited)	December 31, 1999*
Assets	(unaudriced)	
Current assets:		
Cash, cash equivalents and short-		
term investments	\$104,432	\$16,598
Inventories and other current assets	4,881	869
Total current assets	109,313	17,467
Property and equipment, net	4,472	1,271
Intangible assets, net	5,175	1,390
Long-term investments	1,652	2,335
Total assets	\$120,612	\$22,463



\$3,846	\$1,413
407	133
4,253	1,546
1,105	189
115,254	20,728
\$120,612	\$22,463
	407 4,253 1,105 115,254

*derived from audited financial statements. SOURCE DURECT Corporation

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