



DURECT Corporation Reports Fourth Quarter 2002 and Year End Financial Results

CUPERTINO, Calif., Jan. 28 /PRNewswire-FirstCall/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2002.

DURECT's net loss for the three months ended December 31, 2002 was \$8.5 million or 17 cents per share, compared to \$10.1 million or 21 cents per share for the same period in 2001. DURECT's results for the three months ended December 31, 2002 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$103,000, compared to \$1.3 million for the same period in 2001.

DURECT's net loss for the year ended December 31, 2002 was \$37.2 million or 77 cents per share, compared to \$44.9 million or 97 cents per share for the same period in 2001. DURECT's results for the year ended December 31, 2002 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$2.5 million, compared to \$5.3 million for the same period in 2001. DURECT's net loss for the year ended December 31, 2001 included a one-time, non-cash charge of \$14.0 million for acquired in-process research and development associated with the acquisition of Southern BioSystems, Inc.

"Over the past year, we have made significant progress in our product development efforts as we move closer towards our goal of developing products that will improve the quality of life for patients with chronic diseases and enable biotechnology products," stated Jim Brown, President and CEO of DURECT.

"Last year, we stated that our major corporate objectives for 2002 were to sign a commercialization agreement for our lead development program, CHRONOGESIC, and capture value from the additional drug delivery technology platforms acquired by us along with Southern BioSystems."

Dr. Brown added, "Over the last 10 months, we have announced six strategic partnerships using our drug delivery technologies. This includes the announced collaboration with Endo Pharmaceuticals for our CHRONOGESIC product for the U.S. and Canadian markets. These collaborations help to reduce the risk profile of the Company by broadening our product portfolio mix, validating our technology platforms and providing us with a substantial source of funding."

Research and development expenses were \$5.8 million and \$29.6 million for the three months and the year ended December 31, 2002, compared to \$7.9 million and \$24.6 million for the same periods in 2001. The decrease in the three months ended December 31, 2002 was primarily attributable to the reduction in force in November 2002 as a result of an increased focus on cash conservation and product development activities. The increase in fiscal year 2002 was primarily attributable to expanded research and development activities, especially related to preparation and initiation of the company's pivotal Phase III clinical trial and continuing animal toxicological studies for the CHRONOGESIC product. The increase in research and development expenses in fiscal year 2002 was also attributable to continued research and



development of other pharmaceutical systems based on SABER and DURIN technologies and the hiring of additional research and development personnel.

Selling, general and administrative expenses were \$4.0 million and \$11.0 million in the three months and twelve months ended December 31, 2002, compared to \$2.4 million and \$8.8 million for the same periods in 2001. The increases were primarily related to a one-time expense of \$1.7 million for strategic partner advisory services in connection with the Endo partnership in the fourth quarter of 2002.

At December 31, 2002, DURECT had cash and investments of \$48.3 million, including \$2.9 million in restricted investments.

Fourth Quarter and Fiscal Year 2002 Accomplishments

DURECT signed six corporate collaborations in 2002. These collaborations include the following:

- Collaboration with Endo Pharmaceuticals for the CHRONOGESIC product for the treatment in pain management.
- Agreement with Cardinal Health using DURECT's SABER(TM) delivery system to develop long acting oral gel-cap products;
- Development and commercialization agreement with Voyager Pharmaceutical for a DURIN-based Alzheimer's Disease therapy;
- Biotechnology partnership with BioPartners to develop a SABER-based sustained release alpha interferon product for the treatment of Hepatitis C;
- Expansion of an existing licensing agreement with Thorn BioScience to develop selected SABER-based veterinary products. Thorn's first product using the SABER technology has already received approval for the efficacy portion of its NADA. The safety portion of the NADA has also been submitted and the remainder of the filing is expected to be submitted to the FDA this year. This is the first SABER product to be reviewed by the FDA.
- Collaboration with Pain Therapeutics to formulate certain long-acting opioid drugs in oral dosage forms.

First Quarter and Fiscal Year 2003 Financial Guidance

- DURECT expects its net loss will range from \$27.0 million to \$29.0 million or 54 to 58 cents per share for the fiscal year of 2003.
- DURECT's estimates include non-cash charges for the amortization of intangible assets, stock-based compensation and depreciation of



approximately \$4.0 million to \$5.0 million for the fiscal year of 2003.

- DURECT expects its net loss for the first quarter of 2003 will range from \$7.0 million to \$7.5 million or 14 to 15 cents per share.
- Total cash burn for the fiscal year 2003 is expected to be in the range of \$23.0 million to \$25.0 million.

DURECT Corporation (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. In addition to its rights to the CHRONOGESIC product, 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).

NOTE:

CHRONOGESIC(TM), SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners.

The statements in this press release regarding DURECT's products in development and product development plans and projected 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 complete the design, development, and manufacturing process development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, manage relationships with third parties, 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, DURECT's Quarterly Report on Form 10Q for the quarter ended September 30, 2002 filed with the SEC on November 14, 2002 and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

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 BALANCE SHEETS
(in thousands)

December 31, 2002	December 31, 2001 (1)
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Assets

Current assets:

Cash, cash equivalents and short-term investments	\$42,800	\$55,204
Inventories and other current assets	4,241	5,007
Total current assets	47,041	60,211

Property and equipment, net	11,625	13,136
Goodwill	4,716	4,716
Intangible assets, net	4,121	5,462
Long-term investments and other non-current assets	5,468	21,418

Total assets	\$72,971	\$104,943
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Liabilities and stockholders' equity

Current liabilities:

Accounts payable and accrued liabilities	\$4,568	\$5,065
Long-term obligations, current portion	617	683
Total current liabilities	5,185	5,748

Long-term obligations and other	6,604	2,147
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Stockholders' equity	61,182	97,048
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Total liabilities and stockholders' equity	\$72,971	\$104,943
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(1) Derived from audited financial statements.

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

	Quarter ended December 31,		Year ended December 31,	
	2002	2001	2002	2001
	(unaudited)	(unaudited)	(unaudited)	*
Revenue, net	\$2,006	\$1,597	\$7,185	\$6,524
Operating expenses:				
Cost of goods sold (1)	873	850	3,158	3,398
Research and development	5,810	7,889	29,554	24,570
Selling, general and administrative	3,981	2,441	10,970	8,779
Amortization of intangible assets	335	554	1,340	1,844
Stock-based compensation (1)	(243)	701	1,132	3,305
Acquired in-process research and development	--	--	--	14,030



Total operating expenses	10,756	12,435	46,154	55,926
Loss from operations	(8,750)	(10,838)	(38,969)	(49,402)
Other income (expense):				
Interest income	339	837	2,076	4,796
Interest expense	(48)	(85)	(280)	(322)
Net other income	291	752	1,796	4,474
Net loss	\$(8,459)	\$(10,086)	\$(37,173)	\$(44,928)
Net loss per share, basic and diluted	\$(0.17)	\$(0.21)	\$(0.77)	\$(0.97)
Shares used in computing basic and diluted net loss per share	49,251	47,304	48,318	46,414
(1) Stock-based compensation related to the following:				
Cost of goods sold	\$11	\$29	\$72	\$146
Research and development	(321)	438	622	2,235
Selling, general and administrative	78	263	510	1,070
Total stock-based compensation	\$(232)	\$730	\$1,204	\$3,451

Derived from audited financial statements.
SOURCE DURECT Corporation

CONTACT: Schond L. Greenway, Senior Director, Investor Relations and
Strategic Planning of DURECT Corporation, +1-408-777-1417, or
schond.greenway@durect.com