



DURECT Corporation Reports Fourth Quarter 2003 and Year End Financial Results

CUPERTINO, Calif., Feb. 10 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today its financial results for the three months and year ended December 31, 2003.

(Photo: <http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO>)

DURECT's net loss for the three months ended December 31, 2003 was \$5.3 million or 10 cents per share, compared to a net loss of \$8.5 million or 17 cents per share for the same period in 2002. DURECT's results for the three months ended December 31, 2003 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$373,000, compared to \$103,000 for the same period in 2002. Cash used in operating activities was \$6.1 million for the three months ended December 31, 2003, compared to \$8.4 million for the same period in 2002.

DURECT's net loss for the year ended December 31, 2003 was \$22.7 million or 45 cents per share, compared to a net loss of \$37.2 million or 77 cents per share for the same period in 2002. DURECT's results for the year ended December 31, 2003 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$1.2 million, compared to \$2.5 million for the same period in 2002. Cash used in operating activities was \$19.3 million for the year ended December 31, 2003, compared to \$31.3 million for the same period in 2002.

"At present, the Company is implementing improvements to our CHRONOGESIC product to address the premature shutdown. To date, we have completed 30 days of testing with new systems in vitro and in vivo. While we continue to perform additional analyses and generate data around our revised design, we are pleased with the results we have seen thus far. The initial tests from the in vivo studies will be completed by the end of the first quarter. During the course of this year, we will continue our testing, and while we may perform additional enhancements for our CHRONOGESIC product, we remain confident that we will move this program back into the clinic," stated James E. Brown, DVM, President and CEO of DURECT. "We also moved our SABER(TM) post-operative pain relief depot product into the clinic last year. We expect to optimize our formulation to achieve the level of efficacy required for up to 72 hours of post-operative pain relief, and anticipate moving this program into later-stage development this year."

Dr. Brown added, "I'd also like to highlight a significant milestone for our SABER(TM) Technology. Last month, our partner Pain Therapeutics, Inc. began Phase I clinical testing on Remoxy(TM), a novel long-acting oral formulation of oxycodone that utilizes our SABER Technology and which is targeted to decrease the potential for oxycodone abuse. We look forward to the clinical results from this program."

"We feel confident that we will make significant progress in 2004 as we continue to build and advance our product pipeline. In addition, with an estimated \$130 million in potential R&D funding and milestone payments through



the course of our collaborations combined with over \$85 million of cash on our balance sheet, we have the flexibility and liquidity to fund our research, development and commercialization activities.”

Total revenues were \$3.1 million and \$11.8 million for the three months and the year ended December 31, 2003 respectively, compared to \$2.0 million and \$7.2 million for the same periods in 2002. The increase in total revenues was primarily attributable to higher collaborative research and development revenue recognized from DURECT’s agreements with various strategic partners as the Company continued to make progress on the collaboration projects and higher net product sales from DURECT’s product lines.

Research and development expenses were \$4.7 million and \$20.9 million for the three months and the year ended December 31, 2003 respectively, compared to \$5.8 million and \$29.6 million for the same periods in 2002. The decreases were primarily attributable to the lower development costs related to DURECT’s lead product CHRONOGESIC, offset by a slight increase in research and development expenses for our post-operative pain product and other direct expenses incurred under the Company’s collaborative arrangements. The decreases in the research and development expenses also resulted from lower research and development personnel expenses compared with the same periods in 2002.

Selling, general and administrative expenses were \$1.9 million and \$8.5 million for the three months and the year ended December 31, 2003 respectively, compared to \$4.0 million and \$11.0 million for the same periods in 2002. The decrease was primarily attributable to effective cost controls in the existing corporate infrastructure to support all areas of DURECT’s business. In addition, the decrease was due 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, 2003, DURECT had cash and investments of \$85.2 million, including \$3.1 million in restricted investments, compared with total cash and investments of \$48.3 million at December 31, 2002. This increase was primarily due to the net proceeds of approximately \$56.7 million from the sale of \$60.0 million aggregate principal amount of convertible notes in June and July of 2003, offset by cash used in operating activities in the year of 2003.

First Quarter and Fiscal Year 2004 Financial Guidance

- Total cash burn for the fiscal year 2004 is expected to be in the range of \$25.0 million to \$27.0 million, which includes interest payment of \$3.8 million for the convertible notes.
- DURECT expects its net loss will range from \$30.0 million to \$32.0 million or 58 to 62 cents per share for the fiscal year of 2004.
- DURECT’s estimates include non-cash charges for the amortization of intangible assets and stock-based compensation of approximately \$1.3 million to \$1.4 million for the fiscal year of 2004.
- DURECT expects its net loss for the first quarter of 2004 will range from \$7.0 million to \$8.0 million or 14 or 16 cents per share.

About DURECT Corporation

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. DURECT's lead product in development is CHRONOGESIC, a 3-month product for the treatment of chronic pain. DURECT also owns three proprietary drug delivery platform technologies, including the SABER Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system) upon which DURECT is developing a pipeline of other products.

NOTE:

CHRONOGESIC(R), SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of DURECT Corporation. Remoxy(TM) is a trademark of Pain Therapeutics, Inc.

The statements in this press release regarding DURECT's products in development, 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, 2002 filed with the SEC on March 14, 2003, DURECT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 filed with the SEC on November 13, 2003 and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

CHRONOGESIC, the post operative pain product, Remoxy and other products mentioned above are under development by DURECT and have 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)
(unaudited)

	Three months ended		Year ended	
	December 31,		December 31,	
	2003	2002	2003	2002
Product revenue, net	\$1,746	\$1,509	\$6,691	\$6,314
Collaborative research and development and other revenue	1,358	497	5,144	871
Total revenues	3,104	2,006	11,835	7,185
Operating expenses:				



Cost of revenues	587	862	2,427	3,086
Research and development	4,728	5,810	20,948	29,554
Selling, general and administrative	1,895	3,981	8,498	10,970
Amortization of intangible assets	334	335	1,343	1,340
Stock-based compensation(1)	39	(232)	(102)	1,204
Total operating expenses	7,583	10,756	33,114	46,154
Loss from operations	(4,479)	(8,750)	(21,279)	(38,969)
Other income (expense):				
Interest income	309	339	1,041	2,076
Interest expense	(1,089)	(48)	(2,460)	(280)
Net other income (expense)	(780)	291	(1,419)	1,796
Net loss	\$(5,259)	\$(8,459)	\$(22,698)	\$(37,173)
Net loss per share, basic and diluted	\$(0.10)	\$(0.17)	\$(0.45)	\$(0.77)
Shares used in computing basic and diluted net loss per share	50,996	49,251	50,510	48,318
(1) Stock-based compensation related to the following:				
Cost of revenues	\$3	\$11	\$18	\$72
Research and development	16	(321)	(210)	622
Selling, general and administrative	20	78	90	510
	\$39	\$(232)	\$(102)	\$1,204

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEET
(in thousands)

	December 31, 2003	December 31, 2002 (1)
Assets		
Current assets:		
Cash and cash equivalents	\$21,203	\$14,089
Short-term investments	39,511	28,711
Accounts Receivable	1,968	944
Inventories	1,902	1,707
Prepaid expenses and other current assets	1,480	1,590
Total current assets	66,064	47,041
Property and equipment, net	9,316	11,625
Goodwill	6,399	4,716
Intangible assets, net	2,994	4,121
Long-term investments	21,334	2,578
Restricted investments	3,119	2,890
Other non-current assets	3,181	--
Total assets	\$112,407	\$72,971
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$4,551	\$4,568



Long-term obligations, current portion	463	617
Total current liabilities	5,014	5,185
Long-term obligations, noncurrent portion	62,278	1,604
Stockholders' equity	45,115	66,182
Total liabilities and stockholders' equity	\$112,407	\$72,971

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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