



DURECT Corporation Announces First Quarter 2004 Financial Results

CUPERTINO, Calif., April 22 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2004.

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

DURECT's net loss for the three months ended March 31, 2004 was \$6.0 million or 12 cents per share, compared to a net loss of \$5.9 million or 12 cents per share for the same period in 2003. DURECT's results for the three months ended March 31, 2004 included non-cash charges for the amortization of intangible assets and stock-based compensation of \$370,000, compared to \$181,000 for the same period in 2003. Cash used in operating activities was \$4.7 million for the three months ended March 31, 2004, compared to \$5.2 million for the same period in 2003.

"During the quarter, the Company completed feasibility studies to test and measure the performance of a number of alternative prototype systems in animals for our CHRONOGESIC(R) product, which we have partnered with Endo Pharmaceuticals in the U.S. and Canada. Based on the data, we have identified a number of possible solutions to address the premature shutdown. The results thus far give us the confidence that this program remains on track, and we anticipate that we will resume human clinical trials by the end of the year as previously stated," stated James E. Brown, DVM, President and CEO of DURECT.

Dr. Brown continued, "Additionally, we have been formulating our SABER(TM) post-operative pain relief depot product with higher drug loadings in preparation for Phase I/IIA studies anticipated later this year. We are also formulating different compositions for different clinical settings. We held a clinical advisory meeting with our Scientific Advisory Board composed of relevant physician experts and thought leaders, where they provided valuable input into our Phase I/IIA clinical trial protocol design. We are very pleased at the level of interest that this product has received from our clinical advisors, potential partners and physicians currently treating patients who would be targeted for our product."

"During the quarter, Phase I clinical testing began for 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. This product is partnered with Pain Therapeutics, Inc., and we look forward to the clinical results from this program."

Total revenues were \$3.4 million for the three months ended March 31, 2004, compared to \$2.6 million for the same period in 2003. Total collaborative research and development and other revenues were \$2.0 million for the three months ended March 31, 2004, compared with \$1.1 million for the same period in 2003. The increase in total revenues was primarily attributable to higher collaborative research and development revenue recognized from our agreements with Pain Therapeutics, Inc. and Voyager Pharmaceutical Corporation



and higher service revenue from our wholly-owned subsidiary, Absorbable Polymers International Corporation (API), offset by lower product revenues from our ALZET(R) and API product lines.

Research and development expenses were \$5.4 million for the three months ended March 31, 2004, compared to \$5.6 million for the same period in 2003. The decrease in the three months ended March 31, 2004 was primarily attributable to the lower personnel expenses and consulting expenses compared with the same period in 2003.

Selling, general and administrative expenses were \$2.2 million for the three months ended March 31, 2004, compared to \$2.2 million for the same period in 2003. There was no material difference in selling, general and administrative expenses between the quarter ended March 31, 2004 and the quarter ended March 31, 2003.

Interest income was \$304,000 for the three months ended March 31, 2004, compared with \$241,000 for the same period in 2003. The increase in interest income was primarily the result of higher cash and investment balances held during the three months ended March 31, 2004, partially offset by a decline in interest rates. Interest expense was \$1.1 million for the three months ended March 31, 2004 as compared to \$124,000 for the same period in 2003. The increase during the three months ended March 31, 2004 was primarily the result of the interest accrued on the \$60.0 million convertible notes the Company issued in June and July of 2003.

At March 31, 2004, DURECT had cash and investments of \$80.3 million, including \$3.0 million in restricted investments, compared with cash and investments of \$85.2 million at December 31, 2003.

DURECT expects its net loss for the second quarter of 2004 will range from \$7.0 million to \$8.0 million or 14 to 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(R), a 3-month product for the treatment of chronic pain. DURECT also owns three proprietary drug delivery platform technologies, including the SABER(TM) 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), ALZET(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, anticipated clinical trials 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, 2003 filed with the SEC on March 11, 2004, DURECT's Quarterly Report on Form 10Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

CHRONOGESIC, our post operative pain product, Remoxy and other products mentioned above are under development 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)

	Three months ended March 31,	
	2004 (unaudited)	2003 (unaudited)
Product revenue, net	\$1,365	\$1,507
Collaborative research and development and other revenue	2,020	1,074
Total revenues	3,385	2,581
Operating expenses:		
Cost of revenues	565	595
Research and development	5,409	5,572
Selling, general and administrative	2,224	2,243
Amortization of intangible assets	335	335
Stock-based compensation(1)	35	(154)
Total operating expenses	8,568	8,591
Loss from operations	(5,183)	(6,010)
Other income (expense):		
Interest income	304	241
Interest expense	(1,111)	(124)
Net other income (expense)	(807)	117
Net loss	\$(5,990)	\$(5,893)
Net loss per share, basic and diluted	\$(0.12)	\$(0.12)
Shares used in computing basic and		



diluted net loss per share	51,124	50,123
(1) Stock-based compensation related to the following:		
Cost of revenues	\$3	\$8
Research and development	27	(236)
Selling, general and administrative	5	74
	\$35	\$(154)

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2004	December 31, 2003(1)
Assets		
Current assets:		
Cash and cash equivalents	\$21,667	\$21,203
Short-term investments	36,268	39,511
Accounts Receivable	2,626	1,968
Inventories	2,056	1,902
Prepaid expenses and other current assets	1,399	1,480
Total current assets	64,016	66,064
Property and equipment, net	8,792	9,316
Goodwill	6,399	6,399
Intangible assets, net	2,659	2,994
Long-term investments	19,374	21,334
Restricted investments	2,975	3,119
Other non-current assets	3,036	3,181
Total assets	\$107,251	\$112,407
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$5,219	\$4,551
Long-term obligations, current portion	463	463
Total current liabilities	5,682	5,014
Long-term obligations, noncurrent portion	62,214	62,278
Stockholders' equity	39,355	45,115
Total liabilities and stockholders' equity	\$107,251	\$112,407

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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