DURECT Corporation Reports Fourth Quarter and Year End 2004 Financial Results

CUPERTINO, Calif., Feb 10, 2005 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today its financial results for the three months and year ended December 31, 2004.

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

Our net loss for the three months ended December 31, 2004 was $7.0 million or 13 cents per share, compared to a net loss of $5.3 million or 10 cents per share for the same period in 2003. Our results for the three months ended December 31, 2004 included non-cash charges for the amortization of intangible assets and stock-based compensation of $329,000, compared to $373,000 for the same period in 2003. Cash used in operating activities was $6.8 million for the three months ended December 31, 2004, compared to $6.1 million for the same period in 2003.

Our net loss for the year ended December 31, 2004 was $27.6 million or 54 cents per share, compared to a net loss of $22.7 million or 45 cents per share for the same period in 2003. Our results for the year ended December 31, 2004 included non-cash charges for the amortization of intangible assets and stock-based compensation of $1.5 million, compared to $1.2 million for the same period in 2003. Cash used in operating activities was $22.2 million for the year ended December 31, 2004, compared to $19.3 million for the same period in 2003.

“We completed fiscal year 2004 by accomplishing the major objectives for four out of five products in development. We currently have four programs in clinical development, utilizing four different proprietary delivery platforms — transdermal (TRANSDUR(TM)-based sufentanil patch), oral (ORADUR(TM)-based oxycodone), injectable (SABER(TM)-based post-operative pain depot) and biodegradable implantable (DURIN(TM)-based Alzheimer’s disease product),” said James E. Brown, President and CEO of DURECT. “While we were disappointed with the delay in our CHRONOGESIC(R) program, at the same time, we are proud to have advanced four additional programs in to later stage clinical development.”

Dr. Brown continued, “Earlier today, we were pleased to announce that we met two established program milestones. We announced the completion of dosing of the Phase I pharmacokinetic study for our TRANSDUR-based sufentanil patch. We also announced that we have completed dosing of the first cohort of the on-going Phase II trial for our SABER-based post-operative pain relief depot, and we are actively enrolling patients in the second cohort. We continue to receive strong interest from potential commercialization partners for these two programs.”

Fourth Quarter and Fiscal Year 2004 Developments

TRANSDUR-based Sufentanil Pain Product Candidate

— In October 2004, we initiated a Phase I clinical study for our new

proprietary transdermal sufentanil product. The trial consists of a pharmacokinetic study in normal, healthy volunteers in Europe. The objectives of the clinical study are to determine the safety and tolerability of our transdermal sufentanil patch as well as to evaluate the pharmacokinetics of sufentanil following transdermal administration.

— Our transdermal sufentanil product is intended to provide extended chronic pain relief for up to seven days, as compared to the three days of relief provided with currently available opioid patches. Further, we anticipate that the small size of our sufentanil patch (potentially as small as 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience for patients.

SABER-based Post-Operative Pain Depot Product Candidate

— In October 2004, we initiated a Phase II clinical study for our post-operative pain relief depot. This product candidate is a sustained release injectable designed to provide up to 72 hours of post-surgical pain relief and is based on our patented SABER delivery system.

— We anticipate that the trial would enroll approximately 60 patients, with an option to enroll an additional 30 patients.

— The Phase II trial is a dose escalation study, conducted in three cohorts, for the treatment of pain in patients following repair of inguinal hernia. Patients are administered SABER-Bupivacaine at the completion of surgery, and the trial will be used to evaluate the safety and efficacy of the therapy.

— The study end points include a pharmacokinetic evaluation of plasma bupivacaine levels, time to first supplemental analgesic, total supplemental analgesics, and analysis of the sum of pain intensity and total pain relief.

Remoxy(TM) Product Candidate (Collaboration with Pain Therapeutics, Inc.)

— Pain Therapeutics initiated the Phase III program for Remoxy in December 2004.

— Remoxy is a novel long-acting oral formulation of oxycodone based on DURECT’s ORADUR technology, a proprietary oral sustained release technology with several potential abuse deterrent properties.

CHRONOGESIC (Sufentanil) Pain Therapy Product Candidate (Collaboration with Endo Pharmaceuticals)

— We continue to work on the system design of our CHRONOGESIC product in order to resume clinical trials for this product.

— CHRONOGESIC is an osmotic implant that delivers sufentanil for the treatment of chronic pain.

DURIN-based Leuprolide Alzheimer’s Disease Product Candidate (Collaboration with Voyager Pharmaceutical Corporation)

— In December 2004, the FDA accepted an Investigational New Drug Application and clinical protocol submitted by Voyager for a product candidate for treating Alzheimer’s disease using our DURIN(TM) drug delivery platform.

— The trial consists of a pharmacokinetic study in normal, healthy volunteers, the objectives of which are to determine the safety and tolerability of the DURIN implant, as well as to evaluate the pharmacokinetic profile of the active agent (leuprolide acetate) following administration of the product candidate.

— Enrollment of the clinical trial was completed in January 2005.

Total revenues were $4.0 million and $13.9 million for the three months and the year ended December 31, 2004 respectively, compared to $3.1 million and $11.8 million for the same periods in 2003. The increase in total revenues was primarily attributable to higher collaborative research and development and milestone revenue recognized from our agreements with various strategic partners as we continued to make progress on the collaboration programs.

Research and development expenses were $6.2 million and $24.2 million for the three months and the year ended December 31, 2004 respectively, compared to $4.7 million and $20.9 million for the same periods in 2003. The increases were primarily attributable to the higher development costs related to our SABER-based post-operative pain depot, TRANSDUR-based transdermal patch, CHRONOGESIC and other partnered products under development. We initiated clinical trials for both the SABER-based post-operative pain depot product candidate and the TRANSDUR-based transdermal patch product candidate in the fourth quarter of 2004.

Selling, general and administrative expenses were $2.9 million and $9.7 million for the three months and the year ended December 31, 2004 respectively, compared to $1.9 million and $8.5 million for the same periods in 2003. The increases were primarily attributable to direct internal and external expenses, to comply with the Sarbanes-Oxley Act Section 404, approximately $700,000 for fiscal year 2004, and higher employee related costs.

Interest income was $317,000 and $1.2 million for the three months and the year ended December 31, 2004 respectively, compared to $309,000 and $1.0 million for the same periods in 2003. The increase in interest income was primarily the result of higher yields in our cash and investments. Interest expense was $1.2 million and $4.5 million for the three months and the year ended December 31, 2004 respectively, compared with $1.1 million and $2.5 million for the same periods in 2003, which was primarily the result of the interest expense on the $60.0 million convertible notes we issued in June and July of 2003.

At December 31, 2004, we had cash and investments of $61.8 million, including $2.8 million in restricted investments, compared with total cash and investments of $85.2 million at December 31, 2003.

First Quarter and Fiscal Year 2005 Financial Guidance

— We expect total cash burn for the fiscal year 2005 to be in the range of $26.0 million to $28.0 million, which includes interest payment of $3.8 million for the convertible notes.

— We expect our net loss will range from $30.0 million to $32.0 million or 58 to 62 cents per share for the fiscal year of 2005. Our estimates include anticipated non-cash charges for the amortization of intangible assets and

stock-based compensation.

— We expect our net loss for the first quarter of 2005 will range from $9.0 million to $10.0 million or 17 or 19 cents per share.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceuticals systems company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. These platform technologies include the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the ORADUR(TM) sustained release oral gel-cap technology (an oral sustained release technology with several potential abuse deterrent properties), the DURIN(TM) Biodegradable Implant (drug-loaded implant system), the TRANSDUR(TM) transdermal technology and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also partners with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on its technologies. DURECT has five disclosed on-going development programs of which three are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

NOTE: CHRONOGESIC(R), SABER(TM), ORADUR(TM), DURIN(TM), TRANSDUR(TM) and MICRODUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners.

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 these products. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 filed with the SEC on November 5, 2004 under the heading "Factors that may affect future results."

DURECT CORPORATION

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

	Three months ended December 31,		Year ended December 31,	
	2004 (unaudited)	2003 (unaudited)	2004 (unaudited)	2003 (audited)
Product revenue, net	$1,515	$1,746	$6,416	$6,691
Collaborative research and development and				

other revenue	2,508	1,358	7,437	5,144
Total revenues	4,023	3,104	13,853	11,835
Operating expenses:				
Cost of revenues	612	587	2,729	2,427
Research and development	6,213	4,728	24,233	20,948
Selling, general and administrative	2,922	1,895	9,747	8,498
Amortization of intangible assets	303	334	1,249	1,343
Stock-based compensation (1)	26	39	204	(102)
Total operating expenses	10,076	7,583	38,162	33,114
Loss from operations	(6,053)	(4,479)	(24,309)	(21,279)
Other income (expense):				
Interest income	317	309	1,236	1,041
Interest expense and other	(1,200)	(1,089)	(4,546)	(2,460)
Net other expense	(883)	(780)	(3,310)	(1,419)
Loss before income taxes	(6,936)	(5,259)	(27,619)	(22,698)
Income tax provision	18	--	18	--
Net loss	$(6,954)	$(5,259)	$(27,637)	$(22,698)
Net loss per common share, basic and diluted	$(0.13)	$(0.10)	$(0.54)	$(0.45)
Shares used in computing basic and diluted net loss per share	51,839	50,996	51,507	50,510

(1) Stock-based compensation related to the following:				
Cost of revenues	$--	$3	$1	$18
Research and development	1	16	157	(210)
Selling, general and administrative	25	20	46	90
	$26	$39	$204	$(102)

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2004 (unaudited)	December 31, 2003 (audited)
Assets		
Current assets:		

Cash and cash equivalents	$20,032	$21,203
Short-term investments	21,765	39,511
Accounts receivable, net	2,481	1,968
Inventories	1,929	1,902
Prepaid expenses and other current assets	1,364	1,480
Total current assets	47,571	66,064
Property and equipment, net	7,112	9,316
Goodwill	6,399	6,399
Intangible assets, net	1,745	2,994
Long-term investments	17,218	21,334
Restricted investments	2,798	3,119
Other non-current assets	2,625	3,181
Total assets	$85,468	$112,407
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued liabilities and deferred revenue	$5,006	$4,551
Long-term obligations, current portion	483	463
Total current liabilities	5,489	5,014
Long-term obligations, noncurrent portion	61,589	62,278
Stockholders' equity	18,390	45,115
Total liabilities and stockholders' equity	$85,468	$112,407

SOURCE DURECT Corporation

investors, Schond L. Greenway, Executive Director, IR and Strategic Planning, or
media, Melissa M. Ta, Associate Director, Corporate Communications,
both of DURECT
Corporation, +1-408-777-1417