DURECT Corporation Announces First Quarter 2005 Financial Results and Update on Its Development Programs

CUPERTINO, Calif., May 3 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2005.

DURECT's net loss for the three months ended March 31, 2005 was $5.4 million or 10 cents per share, compared to a net loss of $6.0 million or 12 cents per share for the same period in 2004. DURECT's results for the three months ended March 31, 2005 included non-cash charges for the amortization of intangible assets and stock-based compensation of $353,000, compared to $370,000 for the same period in 2004. Cash used in operating activities was $5.2 million for the three months ended March 31, 2005, compared to $4.7 million for the same period in 2004.

"The first quarter of 2005 was an outstanding quarter for DURECT. During the quarter, we achieved all of the product development milestones we had previously announced that we intended to achieve for the period, signed a major development and commercialization agreement and strengthened our financial position by managing our cash burn through collaborative funding and milestones payments. At the beginning of 2005, we had anticipated that our net decrease in cash and investment balance for 2005 would range from $26.0 to $28.0 million. As a result of our agreement with Endo Pharmaceuticals relating to our sufentanil patch, we anticipate that this range will now be between $12.0 million to $14.0 million this year," stated James E. Brown, DVM, President and CEO of DURECT.

Dr. Brown continued, "With respect to our progress on our development programs, today, we are pleased to announce that we have completed dosing of the second cohort of our ongoing Phase II clinical study for our post-operative pain relief depot. Additionally, as we previously announced, during this quarter, enrollment was completed in the on-going Phase I clinical study for our DURIN(TM)-based leuprolide product candidate for the treatment of Alzheimer's disease, in partnership with Voyager Pharmaceuticals."

Dr. Brown added, "As a result of our rapid progress to date on our sufentanil patch program, we established a strong commercialization partnership with Endo Pharmaceuticals on this product candidate in March 2005 for the U.S. and Canadian markets. As part of the agreement, Endo paid us an upfront fee of $10.0 million, with additional anticipated milestone payments of approximately $35.0 million. Endo will be solely responsible for funding the remaining development expenses for this product candidate for the U.S. and Canadian markets. We are also excited to continue to advance our goal of becoming a specialty pharmaceutical company through our right under this agreement to co-promote this product in the chronic pain space alongside such a strong marketing partner."

Year to Date Updates on Development Programs

Post-Operative Pain Relief Depot Product Candidate (SABER-Bupivacaine)

— In May 2005, we completed dosing of the second cohort of the on-going Phase II clinical study for our SABER-Bupivacaine product candidate. This product candidate, based on our patented SABER delivery system, is intended to be administered around a surgical site after surgery to provide 72 hours or more of regional pain relief and is intended to reduce hospital stays and the amount of traditional post-surgical pain medications needed by patients (and therefore the side effects that result from the use of such medications).

— 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 establish the dosing range and 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.

TRANSDUR(TM)-Sufentanil Pain Patch Product Candidate (Collaboration with Endo Pharmaceuticals in the U.S. and Canada)

— In March 2005, we entered into an agreement with Endo Pharmaceuticals, Inc. that grants to Endo the exclusive license to develop and commercialize our seven-day TRANSDUR(TM)-Sufentanil patch product candidate in the U.S. and Canada.

— Our TRANSDUR(TM) sufentanil patch, a one-week treatment for chronic pain, is currently in Phase II studies.

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

— In January 2005, DURECT and Voyager Pharmaceutical announced the completion of enrollment for the Phase I study of our DURIN(TM)-based leuprolide acetate product candidate for Alzheimer's disease currently under development.

— 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.

— As previously announced, Voyager completed dosing of a Phase II dose ranging study of the active agent in women with Alzheimer's disease.

Total revenues were $5.4 million for the three months ended March 31, 2005, compared to $3.4 million for the same period in 2004. Total collaborative research and development and other revenues were $3.6 million for the three months ended March 31, 2005, compared with $2.0 million for the same period in 2004. The increase in total revenues was primarily attributable to higher collaborative research and development revenue recognized from our agreements with Pain Therapeutics, Inc., Voyager Pharmaceutical Corporation

and Endo Pharmaceuticals, Inc. (TRANSDUR-sufentanil) and higher product revenues from our ALZET product lines.

Research and development expenses were $6.6 million for the three months ended March 31, 2005, compared to $5.4 million for the same period in 2004. The increase was primarily attributable to the higher development expenses for SABER-Bupivacaine, TRANSDUR-Sufentanil and partnered product candidates.

Selling, general and administrative expenses were $2.5 million for the three months ended March 31, 2005, compared to $2.2 million for the same period in 2004. The increase in the three months ended March 31, 2005 was primarily due to higher employee costs and external costs to comply with the Sarbanes-Oxley Act.

Interest and other income was $485,000 for the three months ended March 31, 2005, compared with $304,000 for the same period in 2004. The increase in interest income was primarily the result of higher yields on cash and investment balances held during the three months ended March 31, 2005 compared with the same period in 2004. Interest expense was both $1.1 million for the three months ended March 31, 2005 and 2004. The interest expense 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, 2005, DURECT had cash and investments of $55.8 million, including $2.8 million in restricted investments, compared with cash and investments of $61.8 million at December 31, 2004.

Revised Fiscal Year 2005 Financial Guidance

As a result of our collaboration with Endo Pharmaceuticals for our TRANSDUR(TM) sufentanil patch product candidate in the U.S. and Canada, we anticipate that our December 31, 2005 cash and investments balance to be in the range of $48.0 million to $50.0 million, which includes a $10.0 million up-front payment from Endo Pharmaceuticals.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical 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 collaborates 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 four are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

DURECT Forward-Looking Statement

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 (and that of its third party collaborators where applicable) abilities to complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize the product candidate, as well as marketplace acceptance of the product candidate. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the year ended December 31, 2004 filed with the SEC on March 14, 2005 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 March 31,	
	2005 (unaudited)	2004 (unaudited)
Product revenue, net	$1,757	$1,365
Collaborative research and development and other revenue	3,597	2,020
Total revenues	5,354	3,385
Operating expenses:		
Cost of revenues	671	565
Research and development	6,618	5,409
Selling, general and administrative	2,504	2,224
Amortization of intangible assets	303	335
Stock-based compensation(1)	50	35
Total operating expenses	10,146	8,568
Loss from operations	(4,792)	(5,183)
Other income (expense):		
Interest and other income	485	304
Interest expense	(1,120)	(1,111)
Net other loss	(635)	(807)
Net loss	$(5,427)	$(5,990)

Net loss per share, basic and diluted	$(0.10)	$(0.12)
Shares used in computing basic and diluted net loss per share	51,887	51,124
(1) Stock-based compensation related to the following:		
Cost of revenues	$--	$3
Research and development	46	27
Selling, general and administrative	4	5
	$50	$35

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2005	December 31, 2004 (1)
Assets		
Current assets:		
Cash and cash equivalents	$18,472	$20,032
Short-term investments	20,065	21,765
Accounts Receivable	13,958	2,481
Inventories	1,906	1,929
Prepaid expenses and other current assets	1,417	1,364
Total current assets	55,818	47,571
Property and equipment, net	7,213	7,112
Goodwill	6,399	6,399
Intangible assets, net	1,441	1,745
Long-term investments	14,454	17,218
Restricted investments	2,808	2,798
Other non-current assets	2,469	2,625
Total assets	$90,602	$85,468
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued liabilities and deferred revenue	$8,398	$5,006
Long-term obligations, current portion	435	483
Total current liabilities	8,833	5,489
Long-term obligations, noncurrent portion	68,773	61,589
Stockholders' equity	12,996	18,390
Total liabilities and stockholders' equity	$90,602	$85,468

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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