DURECT Corporation Announces Third Quarter 2005 Financial Results

CUPERTINO, Calif., Oct. 13 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2005.

DURECT's net loss for the three months ended September 30, 2005 was $3.0 million or 6 cents per share, compared to a net loss of $7.3 million or 14 cents per share for the same period in 2004. DURECT's results for the three months ended September 30, 2005 included non-cash charges of $363,000 for the amortization of intangible assets and stock-based compensation, compared to $311,000 for the same period in 2004. Cash used in operating activities was $1.1 million for the three months ended September 30, 2005, compared to $4.4 million for the same period in 2004.

"We had a productive third quarter and executed on our corporate objectives. For our ORADUR(TM) sustained release oral gel-cap technology, which is the basis for the Remoxy(TM) product candidate under development by Pain Therapeutics, we announced that Pain Therapeutics has achieved positive results in an initial Phase III study. The data from the first Phase III clinical study for Remoxy reinforces our belief that our ORADUR technology is maturing and has demonstrated a variety of benefits, including the potential to reduce abuse when compared to current commercial long-acting dosage forms, as well as sustained release capabilities. We also completed dosing of the third and final cohort for our Phase II trial for our SABER-Bupivacaine product candidate in Australia, which we believe has the potential to be a significant advancement over the current commercial treatments for post-surgical pain. We look forward to announcing the data from this third cohort during an upcoming medical conference later this month," stated James E. Brown, DVM, President and CEO of DURECT.

Dr. Brown added, "We continue to make significant progress on our other development programs, including our DURIN(TM)-based leuprolide program (the Memryte(TM) implant) under development with Voyager Pharmaceuticals for the treatment of Alzheimer's disease. Voyager has completed an end of Phase II meeting with the FDA and is currently recruiting patients for pivotal Phase III clinical studies using Memryte as an adjunctive therapy with acetyl cholinesterase inhibitors (ACIs) for the treatment of mild to moderate Alzheimer's disease."

Total revenues were $8.6 million for the three months ended September 30, 2005, compared with $3.4 million for the same period in 2004. Total collaborative research and development and other revenues were $5.4 million for the three months ended September 30, 2005, compared with $1.6 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 Endo Pharmaceuticals, Inc. (TRANSDUR-sufentanil), Voyager Pharmaceutical Corporation (Memryte), and Pain Therapeutics, Inc. (Remoxy) and revenue of $1.6 million recognized in connection with our assignment of certain intellectual property rights.

Research and development expenses were $7.0 million for the three months ended September 30, 2005, compared with $6.6 million for the same period in 2004. The increase in the three months ended September 30, 2005 was primarily attributable to the higher development expenses for SABER-Bupivacaine, DURIN-Leuprolide and certain other product candidates, partially offset by lower development expenses for CHRONOGESIC.

Selling, general and administrative expenses were $2.7 million for the three months ended September 30, 2005, compared with $2.3 million for the same period in 2004. The increase in the three months ended September 30, 2005 was primarily due to higher external costs to support the operation of our business and to comply with the Sarbanes-Oxley Act.

Net other expense was $1.0 million for the three months ended September 30, 2005, compared with $796,000 for the same period in 2004. The increase in net other expense in the three months ended September 30, 2005 was primarily due to approximately $403,000 of non-cash debt conversion expense in connection with the early conversion of a portion of our outstanding 6.25% Convertible Subordinated Notes due 2008.

During the third quarter of 2005, we exchanged and cancelled approximately $2.7 million in principal amount of our 6.25% Convertible Subordinated Notes through conversions into our common stock. As of September 30, 2005, the remaining principal balance of our 6.25% Convertible Subordinated Notes due 2008 was $57.3 million.

At September 30, 2005, DURECT had cash and investments of $59.2 million, including $2.1 million in restricted investments, compared with cash and investments of $61.8 million at December 31, 2004. We anticipate that our December 31, 2005 cash and investments balance to be in the range of $48.0 million to $50.0 million.

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 or episodic 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 projected financial results and DURECT's and its collaborative partners' products in development, anticipated product benefits, and clinical trial results and plans 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 successfully enroll and complete clinical trials, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 filed with the SEC on October 13, 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 September 30,		Nine months ended September 30,	
	2005 (unaudited)	2004 (unaudited)	2005 (unaudited)	2004 (unaudited)
Product revenue, net	$1,653	$1,776	$5,299	$4,901
Revenue from sale of intellectual property rights	1,600	--	1,600	--
Collaborative research and development and other revenue	5,369	1,589	15,896	4,929
Total revenues	8,622	3,365	22,795	9,830
Operating expenses:				
Cost of revenues	573	685	1,933	2,117
Research and development	6,964	6,571	21,195	18,020
Selling, general and administrative	2,699	2,262	8,015	6,825
Amortization of intangible assets	303	303	909	946
Stock-based compensation(1)	60	8	453	178
Total operating expenses	10,599	9,829	32,505	28,086
Loss from operations	(1,977)	(6,464)	(9,710)	(18,256)
Other income (expense):				
Interest and other				

income	467	326	1,359	919
Interest expense	(1,095)	(1,122)	(3,329)	(3,346)
Debt conversion expense	(403)	--	(403)	--
Net other income (expense)	(1,031)	(796)	(2,373)	(2,427)
Loss before income taxes	(3,008)	(7,260)	(12,083)	(20,683)
Income tax provision	4	--	4	--
Net loss	$(3,012)	$(7,260)	$(12,087)	$(20,683)
Net loss per share, basic and diluted	$(0.06)	$(0.14)	$(0.23)	$(0.40)
Shares used in computing basic and diluted net loss per share	52,786	51,670	52,240	51,397
(1) Stock-based compensation related to the following:				
Cost of revenues	$--	$--	$ --	$1
Research and development	60	3	106	156
Selling, general and administrative	--	5	347	21
	$60	$8	$453	$178

DURECT CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2005	December 31, 2004 (1)
Assets		
Current assets:		
Cash and cash equivalents, short term investments and restricted investments	$50,044	$41,797
Accounts receivable	5,770	2,481
Inventories	2,124	1,929
Prepaid expenses and other current assets	1,852	1,364
Total current assets	59,790	47,571
Property and equipment, net	7,263	7,112
Goodwill	6,399	6,399
Intangible assets, net	835	1,745
Long-term investments and restricted		

investments	9,196	20,016
Other non-current assets	2,061	2,625
Total assets	$85,544	$85,468
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued liabilities and deferred revenue	$9,457	$5,006
Long-term obligations, current portion	294	483
Total current liabilities	9,751	5,489
Long-term obligations, noncurrent portion	64,912	61,589
Stockholders' equity	10,881	18,390
Total liabilities and stockholders' equity	$85,544	$85,468

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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