DURECT Corporation Announces Fourth Quarter and Year End 2008 Financial Results

CUPERTINO, Calif., Feb. 9 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2008. Total revenues were $6.6 million for the three months ended December 31, 2008 and December 31, 2007. Net loss for the three months ended December 31, 2008 was $19.5 million, compared to a net loss of $7.2 million for the same period in 2007; net loss in the fourth quarter of 2008 included a $13.5 million non-cash write-down associated with a research and development program (Chronogesic(R)) that we are no longer actively pursuing.

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

For the fiscal year ended December 31, 2008, total revenues were $26.0 million, compared to $30.7 million for the same period in 2007. Net loss for the year ended December 31, 2008 was $45.1 million (including the $13.5 million write-down described above), compared to a net loss of $24.3 million for the same period in 2007.

At December 31, 2008, DURECT had cash and investments of $52.7 million, compared with cash and investments of $62.0 million at December 31, 2007, including restricted investments of $1.0 million at December 31, 2008 and 2007. DURECT's net decrease in cash and investments during 2008 was $9.3 million, as compared to a net decrease in cash and investments during 2007 of $19.6 million.

"DURECT continued to advance our late stage pipeline in 2008, licensed ELADUR(TM) on attractive terms including a $20 million upfront payment, and strengthened our balance sheet through the elimination of our convertible debt," stated James E. Brown, D.V.M., President and CEO of DURECT. "Our goals for 2009 include commencing the Phase III program with POSIDUR(TM), advancing our other development programs in clinical studies, and pursuing favorable collaborations around selected programs."

Highlights for DURECT in Fiscal Year 2008 include:

— REMOXY. On June 10, 2008, an NDA for REMOXY (ORADUR(R)-based oxycodone) was submitted to the U.S. Food and Drug Administration (FDA). In August, this NDA filing was accepted and granted Priority Review by the FDA. The FDA typically grants Priority Review to drug candidates that have the potential to demonstrate significant improvements compared to marketed products. Pain Therapeutics, the NDA sponsor and our collaborator, received a Complete Response Letter from the FDA in December 2008 indicating that the NDA is not approved in its present form. Pain Therapeutics has announced that the FDA believes additional non-clinical data will be required to support the approval of REMOXY, but that the FDA has not requested or recommended additional clinical efficacy studies prior to approval.

REMOXY, an investigational drug, is a long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT's ORADUR(R) technology, which is covered by issued patents and pending patent

applications owned by us, REMOXY is designed to resist common methods of prescription drug misuse and abuse.

— POSIDUR (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot. We continue to be in dialogue with the FDA regarding the Phase III program and believe we are making progress in defining that program. In parallel with these discussions, we and our European collaborator, Nycomed, continue to advance development of this drug candidate. As one element in advancing the program, because an orthopedic surgical model will be part of our proposed studies for regulatory approval, in December 2008 we commenced a 60-patient Phase IIb study in Australia using a 5 mL dose in shoulder surgery intended to allow us to confirm aspects of our clinical study design and conduct. Additionally, Nycomed prepared to commence Phase IIb studies in surgical models in Europe. These studies will contribute to the total number of patient exposures that will ultimately be required by the FDA and the European Medicines Agency (EMEA) as part of the product approval process in the U.S. and Europe.

POSIDUR is our post-operative pain relief depot that utilizes our patented SABER technology to deliver bupivacaine to provide up to three days of pain relief after surgery. POSIDUR is licensed to Nycomed for commercialization in Europe and select other countries, and we have retained commercialization rights in the US, Canada and Asia.

— ELADUR (TRANSDUR(TM)-Bupivacaine). During 2008, DURECT presented data showing improved pain control with ELADUR versus placebo over the three day treatment period in a Phase IIa study. We also received Orphan Drug Designation, such that if ELADUR is the first bupivacaine product approved for Post-Herpetic Neuralgia (PHN), ELADUR will receive seven years of market exclusivity for PHN following its approval by the FDA.

In September 2008, we entered into a development and license agreement with Alpharma Ireland Ltd., an affiliate of Alpharma, Inc., granting Alpharma exclusive worldwide rights to develop and commercialize ELADUR. This Agreement became effective in October 2008 after passing clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Under this agreement, Alpharma paid us an upfront license fee of $20 million in the fourth quarter of 2008, with possible additional payments of up to $93 million upon the achievement of predefined development and regulatory milestones spread over multiple clinical indications and geographical territories as well as possible additional payments of up to $150 million in sales-based milestones. If ELADUR is commercialized, DURECT would also receive royalties on product sales. Alpharma will control and fund the further development program. Alpharma, Inc., including its rights and obligations under our agreement, was acquired by King Pharmaceuticals in December 2008.

ELADUR is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application.

— TRANSDUR-Sufentanil. Endo Pharmaceuticals, our licensee for commercialization of TRANSDUR-Sufentanil in the US and Canada, completed Phase II studies designed to evaluate the conversion of patients on oral opioids to TRANSDUR-Sufentanil during 2008.

TRANSDUR-Sufentanil is our proprietary transdermal patch intended to deliver sufentanil to chronic pain sufferers for a period of up to seven days from a single application.

— Reduction in Convertible Notes. Our balance sheet was strengthened during 2008 by the elimination of all of our $23.6 million of convertible debt, which was converted into common stock in June 2008 per the original terms of our indenture.

Financial Guidance for 2009 and Major Potential Milestones over the Next 12-18 Months

— Financial Guidance. Our net cash consumption is heavily influenced by the timing and structure of new corporate collaborations, as well as the achievement of milestones under existing collaborations. While we anticipate entering into new collaborations in 2009 and beyond, assuming no new collaborations, no milestone payments and aggressive funding of our R&D programs, many of which are in clinical development, we anticipate our net cash consumption in 2009 will be approximately $28-32 million.

— Business Development Activities. We have multiple late stage programs that may potentially be partnered over the next 12-18 months. These include TRANSDUR-Sufentanil for Europe and for Asia, POSIDUR for the United States and Asia, as well as various internal programs which we have not described publicly in detail.

— REMOXY. According to Pain Therapeutics, they and their outside technical advisors are evaluating the FDA Complete Response Letter and plan to meet with the FDA in Q2 2009. Pain Therapeutics believes this will provide them with a more reliable context in which to make projections about REMOXY.

— POSIDUR. While not designed for statistical significance, we anticipate having results from our on-going Phase IIb shoulder study by mid-2009. We are continuing our dialogue with the FDA regarding our Phase III program, and anticipate commencing that program in 2009.

— ELADUR. As the next step in developing this product candidate, we anticipate that a Phase IIb study in PHN will be commenced in 2009.

— TRANSDUR-Sufentanil Patch. Endo Pharmaceuticals, our licensee for commercialization of TRANSDUR-Sufentanil in the US and Canada, has stated that they expect to hold an End-of-Phase II meeting with the FDA in early 2009.

Earnings Conference Call

A live audio webcast of a conference call to discuss 2008 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on February 9 and is available by accessing DURECT's homepage at http://www.www.durect.com and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

About DURECT Corporation

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(TM), and

TRANSDUR(TM)-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit http://www.www.durect.com.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(TM), and ELADUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release under the heading "Financial Guidance for 2009 and Major Potential Milestones over the Next 12-18 Months," other statements regarding development and potential uses of REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil, and potential milestone payments or royalties based on the sale of such products 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, delays and additional costs due to requirements imposed by regulatory agencies, DURECT's (and that of its third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to its development activities and products, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, consummate collaborative agreements relating to our product candidates and technologies, manufacture and commercialize the referenced product candidates, obtain marketplace acceptance of the referenced product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund its growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on November 4, 2008 under the heading "Risk Factors."

DURECT CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2008	2007	2008	2007
Collaborative research and development revenue	$4,715	$4,559	$17,192	$22,417
Product revenue, net	1,867	2,026	8,765	8,258
Total revenues	6,582	6,585	25,957	30,675
Operating expenses:				
Cost of revenues (1)	691	807	3,365	3,225
Research and development (1)	8,456	9,502	39,411	38,342
Selling, general and				

administrative (1)	3,684	3,262	15,462	13,618
Write down of deferred royalties and commercial rights	13,480	-	13,480	-
Amortization of intangible assets	13	8	48	31
Total operating expenses	26,324	13,579	71,766	55,216
Loss from operations	(19,742)	(6,994)	(45,809)	(24,541)
Other income (expense):				
Interest and other income	262	753	1,547	3,545
Interest expense	(16)	(475)	(789)	(2,625)
Debt conversion expense	-	(495)	-	(718)
Net other income (expense)	246	(217)	758	202
Net loss	$(19,496)	$(7,211)	$(45,051)	$(24,339)
Net loss per share, basic and diluted	$(0.24)	$(0.10)	$(0.58)	$(0.35)
Shares used in computing basic and diluted net loss per share	81,927	73,641	78,332	70,483

(1) Includes stock-based compensation related to the following:

Cost of revenues	$25	$32	$135	$130
Research and development	1,308	995	5,575	4,286
Selling, general and administrative	722	553	2,790	2,273
Total stock-based compensation	$2,055	$1,580	$8,500	$6,689

DURECT CORPORATION
Condensed Balance Sheet
(in thousands)

	As of December 31, 2008 (unaudited)	As of December 31, 2007(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$29,445	$37,589
Short-term investments	20,836	19,710
Accounts receivable	4,055	3,622
Inventories	3,475	1,963
Prepaid expenses and other current assets	1,849	1,904
Total current assets	59,660	64,788
Property and equipment, net	5,971	7,658

Goodwill	6,399	6,399
Intangible assets, net	157	180
Long-term investments	1,362	3,697
Restricted Investments	1,049	1,020
Other non-current assets	276	278
Total assets	$74,874	$84,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,018	$1,834
Accrued liabilities	5,204	5,499
Contract research liability	995	1,946
Interest payable on convertible notes	-	61
Deferred revenue, current portion	9,033	5,728
Equipment financing obligations, current portion	43	38
Bonds payable, current portion	240	225
Convertible subordinated notes due 2008	-	23,599
Other short-term liabilities	148	158
Total current liabilities	16,681	39,088
Bond payable and equipment financing obligations, noncurrent portion	60	343
Deferred revenue, noncurrent portion	21,118	9,268
Other long-term liabilities	596	740
Stockholders' equity	36,419	34,581
Total liabilities and stockholders' equity	$74,874	$84,020

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

02/09/2009
CONTACT: Matt Hogan, Chief Financial Officer of DURECT Corporation,
+1-408-777-4936
Photo: NewsCom: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO
AP Archive: http://photoarchive.ap.org
PRN Photo Desk, photodesk@prnewswire.com
Web site: http://www.www.durect.com