DURECT Corporation Announces Fourth Quarter and Year End 2007 Financial Results

CUPERTINO, Calif., Feb. 5 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2007. Total revenues were $6.6 million for the three months ended December 31, 2007, compared to $5.4 million for the same period in 2006. Net loss for the three months ended December 31, 2007 was $7.2 million, compared to a net loss of $9.8 million for the same period in 2006.

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

For the fiscal year ended December 31, 2007, total revenues were $30.7 million, compared to $21.9 million for the same period in 2006. Net loss for the year ended December 31, 2007 was $24.3 million, compared to a net loss of $33.3 million for the same period in 2006.

At December 31, 2007, DURECT had cash and investments of $62.0 million, compared with cash and investments of $81.6 million at December 31, 2006; these figures include restricted investments of $1.0 million at December 31, 2007 and $1.3 million at December 31, 2006. DURECT's net decrease in cash during 2007 was $19.6 million.

"DURECT's pipeline advanced during 2007, reporting positive clinical trial results for three programs in Phase III or II. We expect to continue this progress in 2008 as we look forward to the filing of the first New Drug Application (NDA) based on our ORADUR(TM) technology and further advancing our late stage programs," stated James E. Brown, D.V.M., President and CEO of DURECT. "Remoxy(TM) met the primary endpoint in its pivotal Phase III study conducted under a Special Protocol Assessment (SPA), POSIDUR(TM) reported statistically significant improvements in pain control while reducing the use of narcotics in a Phase IIb hernia study, and ELADUR(TM) showed improved pain control versus placebo over the three day treatment period in a Phase IIa study. Each of these programs addresses large market opportunities with product features that offer clear advantages over existing therapeutics."

Highlights for DURECT in Fiscal Year 2007 include:

— Remoxy. In December, our collaborators King Pharmaceuticals and Pain Therapeutics announced that the pivotal Phase III trial for Remoxy successfully met its primary endpoint ($p<0.01$) that was prospectively defined by the U.S. Food and Drug Administration (FDA) during the SPA process. In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia ($p<0.01$) and Global Assessment ($p<0.01$). No drug related safety issues were noted in the study.

Remoxy is an abuse-resistant, long-acting form of oxycodone based on our ORADUR(TM) technology intended for the treatment of chronic pain.

— POSIDUR Post-Operative Pain Relief Depot. In July, we announced positive results from a 122 patient Phase IIb clinical trial in which

POSIDUR at a dose of 5 mL demonstrated statistically significant reductions in post-operative pain (by approximately 30% versus placebo) and in total consumption of supplemental opioid analgesic medications (approximately 3x less versus placebo) in patients undergoing inguinal hernia repair. These successful results triggered an $8 million milestone payment by Nycomed to DURECT under the parties' international collaborative agreement. We have held an end-of-Phase II meeting with the U.S. Food & Drug Administration (FDA) and are in dialogue with the FDA regarding the Phase III program. Hospira, our manufacturer of POSIDUR, has produced supplies for Phase III clinical trials.

POSIDUR is our post-operative pain relief depot that utilizes our patented SABER(TM) 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 DURECT has retained commercialization rights in the US, Canada and Asia.

— ELADUR (TRANSDUR(TM)-Bupivacaine). In December, we announced positive results from a 60 patient Phase IIa clinical trial. In this study of patients suffering from post-herpetic neuralgia, ELADUR showed improved pain control versus placebo during the 3-day continuous treatment period. In addition, ELADUR appeared to be well tolerated overall, and patients treated with ELADUR and placebo exhibited similar safety profiles. We have in place a relationship with Corium International, whereby Corium will be our worldwide supplier of ELADUR patches.

ELADUR is our proprietary transdermal patch intended to provide bupivacaine for a period of up to three days from a single application. We retain full commercial rights to this drug candidate.

— TRANSDUR-Sufentanil. Endo Pharmaceuticals, our licensee for commercialization in the US and Canada, has publicly disclosed that they have commenced their Phase II program in June 2007.

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

— Expansion of Patent Portfolio. In the fourth quarter of 2007, we acquired from a third party a portfolio of worldwide patents relating to drug delivery technologies. This portfolio consists of approximately 22 issued and pending U.S. patents and patent applications as well as their international counterparts. We believe this portfolio will benefit our business by broadening our drug delivery technology base and strengthening our intellectual property position.

— Reduction in Convertible Notes. We reduced the balance of our outstanding convertible notes from $37.3 million at December 31, 2006 to $23.6 million as of December 31, 2007 by paying a small premium over the future interest payments due on these notes in order to induce early conversion. The outstanding convertible notes will mature on June 15, 2008, if not converted earlier.

Financial Guidance for 2008 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 2008 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 2008 will be approximately $32-36 million.

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

— Remoxy. Our collaborator, Pain Therapeutics, has stated that they expect to file the NDA for Remoxy in Q2 2008.

— POSIDUR. We are continuing our dialogue with the FDA regarding our Phase III program, upon completion of which we plan to commence that program.

— ELADUR. We are conducting manufacturing scale-up and processing to secure Phase III supplies, and are developing our clinical and regulatory strategy.

— TRANSDUR-Sufentanil Patch. Endo Pharmaceuticals is continuing to conduct Phase II studies with TRANSDUR-Sufentanil designed to evaluate the conversion of patients on oral opioids to TRANSDUR-Sufentanil.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company developing pharmaceutical systems based on its proprietary drug delivery platform technologies. The Company currently has a number of late-stage pharmaceutical products in development addressing large markets in pain management, with a number of research programs underway targeting chronic disease and other therapeutic areas. For more information, please visit http://www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the anticipated filing of an NDA for Remoxy, our anticipated commencement of the Phase III program for POSIDUR, our possible entry into future collaborative agreements and our projected financial results as well as other statements regarding DURECT's products in development, product development plans, anticipated regulatory, clinical and development milestones and timing thereof, future clinical trial results, our business development intentions and DURECT's emergence as a specialty pharmaceutical company 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 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 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 8, 2007 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,	
	2007	2006	2007	2006
Collaborative research and development revenue	$4,559	$3,522	$14,417	$13,786
Milestone revenue	-	-	8,000	-
Product revenue, net	2,026	1,919	8,258	8,108
Total revenues	6,585	5,441	30,675	21,894
Operating expenses:				
Cost of revenues (1)	807	983	3,225	3,248
Research and development (1)	9,502	11,598	38,342	37,241
Selling, general and administrative (1)	3,262	2,877	13,618	12,417
Amortization of intangible assets	8	8	31	424
Total operating expenses	13,579	15,466	55,216	53,330
Loss from operations	(6,994)	(10,025)	(24,541)	(31,436)
Other income (expense):				
Interest and other income	753	991	3,545	3,832
Interest expense	(475)	(717)	(2,625)	(3,436)
Debt conversion expense	(495)	-	(718)	(2,287)
Net other income (expense)	(217)	274	202	(1,891)
Net loss	$(7,211)	$(9,751)	$(24,339)	$(33,327)
Net loss per share, basic and diluted	$(0.10)	$(0.14)	$(0.35)	$(0.51)
Shares used in computing basic and diluted net loss per share	73,641	68,980	70,483	65,961

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

Cost of revenues	$32	$28	$130	$75
Research and development	995	801	4,286	2,885
Selling, general and administrative	553	420	2,273	1,431
Total stock-based compensation	$1,580	$1,249	$6,689	$4,391

DURECT CORPORATION
Condensed Balance Sheet
(in thousands)

	As of December 31, 2007 (unaudited)	As of December 31, 2006 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$37,589	$41,554
Short-term investments	19,710	28,297
Accounts receivable	3,622	2,152
Inventories	1,963	2,052
Prepaid expenses and other current assets	1,904	1,744
Total current assets	64,788	75,799
Property and equipment, net	7,658	7,451
Goodwill	6,399	6,399
Intangible assets, net	180	111
Long-term investments	3,697	10,472
Restricted Investments	1,020	1,284
Other non-current assets	278	969
Total assets	$84,020	$102,485
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,834	$864
Accrued liabilities	5,499	4,522
Contract research liability	1,946	1,624
Interest payable on convertible notes	61	97
Deferred revenue, current portion	5,728	5,348
Equipment financing obligations, current portion	38	34
Bonds payable, current portion	225	210
Convertible subordinated notes due 2008	23,599	-
Other short-term liabilities	158	-
Total current liabilities	39,088	12,699
Bond payable and equipment financing obligations, noncurrent portion	343	606
Convertible subordinated notes due 2008	-	37,337
Deferred revenue, noncurrent portion	9,268	14,507

Other long-term liabilities	740	304
Stockholders' equity	34,581	37,032
Total liabilities and stockholders' equity	$84,020	$102,485

(1) Derived from audited financial statements.

SOURCE DURECT Corporation
02/05/2008
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