DURECT Corporation Announces Fourth Quarter and Year End 2009 Financial Results

CUPERTINO, Calif., Feb 24, 2010 /PRNewswire via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2009. Total revenues were $4.9 million for the three months ended December 31, 2009 and $7.7 million for the three months ended December 31, 2008. Net loss for the three months ended December 31, 2009 was $9.0 million, compared to a net loss of $18.4 million for the same period in 2008 which 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, 2009, total revenues were $24.3 million, compared to $27.1 million for the same period in 2008. Net loss for the year ended December 31, 2009 was $30.7 million, compared to a net loss of $43.9 million for the same period in 2008 (including the $13.5 million write-down described above).

At December 31, 2009, we had cash and investments of $41.6 million, compared to cash and investments of $52.7 million at December 31, 2008.

“We advanced our late stage pipeline in 2009, most notably through the recent initiation of BESST, our pivotal U.S. Phase III clinical study for POSIDUR(TM), and through work by King Pharmaceuticals to prepare the NDA resubmission for REMOXY(TM),” stated James E. Brown, D.V.M., President and CEO of DURECT. “Our goals for 2010 include enrolling patients in POSIDUR’s Phase III program, assisting King with aspects of the REMOXY NDA resubmission, advancing our other development programs, and establishing favorable licensing collaborations.”

Highlights for DURECT in Fiscal Year 2009 and Major Potential Milestones over the Next 12-18 Months:

— REMOXY. In March 2009, King Pharmaceuticals assumed responsibility for the REMOXY New Drug Application (NDA) from Pain Therapeutics. In July 2009, King met with the FDA to discuss the Complete Response Letter received in December 2008 regarding the REMOXY NDA. According to King, it anticipates that it will resubmit the NDA for REMOXY intended to address all FDA comments in the Complete Response Letter in 2010. During the third quarter of 2009, we entered into an exclusive long term excipient supply agreement with King. This agreement stipulates the terms and conditions under which we will supply to King two key excipients used in the manufacture of REMOXY, based on DURECT’s manufacturing cost plus a specified percentage mark-up.

REMOXY, an investigational drug, is a unique 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. In December 2009, we reported positive top-line results from our Phase IIb clinical study in shoulder surgery of 60 patients. In addition, Nycomed continued enrollment in a Phase IIb study in hysterectomy patients and a Phase IIb study in shoulder surgery patients.

In January 2010, we announced that we had commenced our U.S. pivotal Phase III clinical study known as BESST (Bupivacaine Effectiveness and Safety in SABER(TM) Trial). We expect to complete enrollment of BESST, comprising approximately 300 patients, in the first half of 2011. In Europe, we expect to have top-line data in 2010 from the Phase IIb hysterectomy study being conducted by Nycomed and, depending on the pace of enrollment, potentially from the Phase IIb study in shoulder surgery.

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 other defined countries, and we have retained commercialization rights in the U.S., Canada, Japan and all other countries. In February 2010, we amended our agreement with Nycomed to separate funding and control of the U.S. and European clinical programs and to expand the territory licensed to Nycomed. The parties are not altering the final decision making authority and financial responsibility for the remainder of the development activities, such as the non-clinical and CMC (Chemistry, Manufacturing and Control) activities, which will continue to be jointly managed and funded by Nycomed and us. We are in active discussions with multiple potential partners regarding licensing of the U.S./Canadian and Japanese rights to this program.

— ELADUR (TRANSDUR(TM)-Bupivacaine). In October 2008, worldwide rights to this program were licensed to Alpharma, which was acquired by King Pharmaceuticals in December 2008. During 2009, we and King focused on details associated with next steps in the clinical program, a Phase IIb study which King expects to initiate in the first half of 2010.

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

— TRANSDUR-Sufentanil. In February 2009, a successful end-of-Phase II meeting with the FDA was conducted for this program outlining a potential regulatory pathway for the Phase III program and NDA submission. During 2009, we transitioned the program back to our control. We are in active discussions with multiple potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights. Pending licensing of this drug candidate or other programs, the next step would be the commencement of Phase III for this drug candidate.

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.

— ORADUR-ADHD Program. In August 2009, we signed a development and license agreement with Orient Pharma related to a drug candidate based on our ORADUR Technology and one specified active pharmaceutical ingredient for the treatment of attention deficit hyperactivity disorder (ADHD). Under this agreement, the parties will collaborate to perform a clinical development program through a Phase II study intended to produce a data package that will support later stage development of the drug candidate and subsequent licensing by DURECT. We will be responsible for formulation and study design of the

pre-defined clinical program, which Orient Pharma will fund and execute. We expect to commence Phase I studies during 2010 with this program.

— Feasibility Projects. During 2009, we signed multiple new feasibility projects with pharmaceutical and biotechnology companies whereby we will apply our SABER and DURIN(TM) technologies to both small molecule and biologic agents of interest to our collaborators. We undertake these feasibility projects as a means of demonstrating that our technologies can achieve the drug delivery objectives set forth by our collaborators and are worthy of further development. During 2010, we anticipate establishing and commencing additional feasibility projects with biotechnology and pharmaceutical company collaborators utilizing our drug delivery technologies.

— 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 2010 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 2010 will be approximately $23-27 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 worldwide rights, POSIDUR for the United States/Canada and Japan, as well as various internal programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss 2009 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on February 24 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), ELADUR(TM), and DURIN(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 U.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding our anticipated net cash consumption, the anticipated resubmission of the REMOXY NDA, anticipated clinical trials (including timing and results) for POSIDUR, TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD and our other drug candidates, the potential benefits and uses of our drug candidates and potential collaborations with third parties 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 2, 2009 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,	
	2009	2008	2009	2008
Collaborative research and development and other revenue	$2,802	$5,859	$12,180	$18,336
Product revenue, net	2,076	1,867	12,113	8,765
Total revenues	4,878	7,726	24,293	27,101
Operating expenses:				
Cost of revenues (1)	848	691	5,343	3,365
Research and development (1)	9,546	8,456	34,913	39,411
Selling, general and administrative (1)	3,548	3,697	15,136	15,510
Write down of deferred royalties and commercial rights	-	13,480	-	13,480
Total operating expenses	13,942	26,324	55,392	71,766
Loss from operations	(9,064)	(18,598)	(31,099)	(44,665)
Other income (expense):				
Interest and other income	53	262	420	1,547
Interest and other expense	(5)	(16)	(36)	(789)
Net other income	48	246	384	758

Net loss	$(9,016)	$(18,352)	$(30,715)	$(43,907)
Net loss per share, basic and diluted	$(0.10)	$(0.22)	$(0.37)	$(0.56)
Shares used in computing basic and diluted net loss per share	86,720	81,927	83,427	78,332

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

Cost of revenues	$96	$25	$382	$135
Research and development	1,104	1,308	6,377	5,575
Selling, general and administrative	656	722	3,476	2,790
Total stock-based compensation	$1,856	$2,055	$10,235	$8,500

DURECT CORPORATION
Condensed Balance Sheet
(in thousands)

	As of December 31, 2009 (unaudited)	As of December 31, 2008 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$8,287	$29,445
Short-term investments	32,834	20,836
Short-term restricted investments	-	624
Accounts receivable	1,700	4,055
Inventories	2,799	3,474
Prepaid expenses and other current assets	1,433	1,850
Total current assets	47,053	60,284
Property and equipment, net	3,808	5,971

Goodwill	6,399	6,399
Intangible assets, net	108	157
Long-term investments	-	1,362
Long-term restricted Investments	431	425
Other long-term assets	352	276
Total assets	$58,151	$74,874
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,019	$1,018
Accrued liabilities	5,764	5,204
Contract research liability	990	995
Deferred revenue, current portion	4,703	9,235
Other short-term liabilities	208	431
Total current liabilities	12,684	16,883
Deferred revenue, noncurrent portion	17,543	19,771
Other long-term liabilities	508	656
Stockholders' equity	27,416	37,564
Total liabilities and stockholders' equity	$58,151	$74,874

(1) Derived from audited financial statements.

SOURCE DURECT Corporation