DURECT Corporation Announces First Quarter 2010 Financial Results

CUPERTINO, Calif., May 10, 2010 /PRNewswire via COMTEX/ –DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2010. Total revenues were $7.7 million for the three months ended March 31, 2010 and $6.2 million for the three months ended March 31, 2009. Net loss for the three months ended March 31, 2010 was $6.6 million, compared to a net loss of $8.7 million for the same period in 2009.

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

At March 31, 2010, we had cash and investments of $35.8 million, compared to cash and investments of $41.6 million at December 31, 2009.

“Our late stage pipeline continues to advance in 2010. Of note, BESST, our pivotal U.S. Phase III clinical study for POSIDUR(TM), is well underway. With respect to our partnered programs, King Pharmaceuticals is preparing the NDA resubmission for REMOXY(R) by year-end and has initiated a Phase IIb clinical study of ELADUR(TM) in chronic low back pain,” stated James E. Brown, D.V.M., President and CEO of DURECT.

Recent Highlights:

-- 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 in the fourth quarter of 2010 it will resubmit the NDA for REMOXY intended to address all FDA comments in the Complete Response Letter.
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 the first quarter of 2010 we continued to enroll patients in our U.S. pivotal Phase III clinical study known as BESST (Bupivacaine Effectiveness and Safety in SABER Trial). We expect to complete enrollment of BESST, comprising approximately 300 patients, in the first half of 2011.
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 discussions with 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. In April 2010, King Pharmaceuticals initiated a Phase IIb trial evaluating the safety and efficacy of ELADUR in patients with chronic low back pain. King expects to enroll approximately 260 patients in this study.
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 discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.
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.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2010 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 10 and is available by accessing DURECT's homepage at 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 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 the anticipated resubmission of the REMOXY NDA, our U.S. pivotal Phase III clinical trial (BESST) for POSIDUR and Phase IIb trial for ELADUR including anticipated patient enrollment numbers and timing thereof, 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 on our drug candidates, unexpected results and adverse events from clinical trials for our drug candidates, 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 our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K on March 4, 2010 under the heading "Risk Factors."

DURECT CORPORATION
STATEMENT OF OPERATIONS DATA
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31,	
	2010	2009
Collaborative research and development and other revenue	$3,816	$3,745
Product revenue, net	3,850	2,415
Total revenues	7,666	6,160
Operating expenses:		
Cost of product revenues (1)	1,378	824
Research and development (1)	9,421	9,903
Selling, general and administrative (1)	3,502	4,257
Total operating expenses	14,301	14,984
Loss from operations	(6,635)	(8,824)
Other income (expense):		

Interest and other income	11	179
Interest and other expense	(2)	(11)
Net other income	9	168
Net loss	$(6,626)	$(8,656)
Net loss per share, basic and diluted	$(0.08)	$(0.11)
Shares used in computing basic and diluted net loss per share	86,756	82,023

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

Cost of product revenues	$84	$78
Research and development	1,277	2,281
Selling, general and administrative	669	1,171
Total stock-based compensation	$2,030	$3,530

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of March 31, 2010 (unaudited)	As of December 31, 2009 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$3,529	$8,287
Short-term investments	31,827	32,834
Short-term restricted investments	66	-
Accounts receivable	3,603	1,700
Inventories	2,651	2,799
Prepaid expenses and other current assets	1,712	1,433
Total current assets	43,388	47,053

Property and equipment, net	3,158	3,808
Goodwill	6,399	6,399
Intangible assets, net	96	108
Long-term restricted Investments	366	431
Other long-term assets	344	352
Total assets	$53,751	$58,151
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,018	$1,019
Accrued liabilities	5,246	5,337
Contract research liability	1,421	990
Deferred revenue, current portion	4,530	4,703
Other short-term liabilities	220	208
Total current liabilities	12,435	12,257
Deferred revenue, noncurrent portion	16,430	17,543
Other long-term liabilities	447	508
Stockholders' equity	24,439	27,843
Total liabilities and stockholders' equity	$53,751	$58,151

(1) Derived from audited financial statements.