DURECT Corporation Announces First Quarter 2011 Financial Results and Update of Programs

CUPERTINO, Calif., May 5, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2011. Total revenues increased to $8.6 million for the three months ended March 31, 2011 from $7.7 million for the three months ended March 31, 2010. Net loss for the three months ended March 31, 2011 was $6.4 million, compared to a net loss of $6.6 million for the same period in 2010.

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

At March 31, 2011, we had cash and investments of $41.9 million, compared to cash and investments of $49.6 million at December 31, 2010.

“We are pleased that an experienced and professional organization such as Pfizer is handling the REMOXY® NDA resubmission, and if approved, the marketing of REMOXY,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, our pivotal Phase III trial for POSIDUR(TM) (BESST) is approaching completion of enrollment with top-line data anticipated this year. These two most advanced programs are complemented by a diverse pipeline of other product candidates which we are progressing in the pain and ADHD markets.”

Update of Programs:

- **REMOXY.** The U.S. Food and Drug Administration (FDA) has set a June 23, 2011 PDUFA goal date for the REMOXY New Drug Application (NDA) which was resubmitted in December 2010 by King Pharmaceuticals (King) following a Complete Response Letter received by Pain Therapeutics in December 2008. Pfizer completed its acquisition of King in February 2011. During Pfizer’s first quarter earnings call on May 3, Pfizer stated that it was working to address a specific issue in the manufacturing section of the REMOXY application, as well as to understand any potential implications of FDA’s recent class-wide REMS announcement for extended release opioids. Pfizer stated that these issues could delay the timing of approval or the launch of REMOXY. As a result of its acquisition of King, Pfizer has assumed the development and commercialization rights and obligations to REMOXY.

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® 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. An abuse liability study was recently published in Pain Medicine, the Official Journal of the American Academy of Pain Medicine. In this study of REMOXY versus Oxycodone ER tested in volunteers with a history of opioid abuse, REMOXY met all prospectively defined primary endpoints. See “The Abuse Potential of Remoxy®, an Extended-Release Formulation of Oxycodone, Compared with Immediate- and Extended-Release Oxycodone” (Pain Medicine 2011; 12; 618-631). This study complements previously published data on the extraction under various conditions of oxycodone from REMOXY; see “Remoxy®: A Novel Formulation of Extended-Release Oxycodone Developed Using the ORADUR® Technology” (The Journal of Applied Research, Vol.10, No.3, 2010) which is accessible on DURECT’s website at www.www.durect.com/wt/durect/page_name/Publications.

- **POSIDUR (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot** During the first quarter of 2011, we continued enrolling 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 third quarter of 2011 with top-line data anticipated in the fourth quarter of 2011. Based on a pooled and blinded analysis of the variability of data within BESST, we do not plan to increase the size of the study.

In February 2011, we announced results from a shoulder surgery Phase II study conducted in Europe by Nycomed. At that time, we and Nycomed amended our agreement such that, for an interim period, DURECT will have full control and financial responsibility for

non-clinical and CMC activities which had been previously jointly controlled and funded by DURECT and Nycomed. If Nycomed elects to continue European development of POSIDUR after evaluation of BESST data, under the terms of the amendment, DURECT and Nycomed would resume joint control and financial responsibility of the non-clinical and CMC activities for the E.U. and the U.S.

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 Hospira for commercialization in the U.S. and Canada, and to Nycomed for commercialization in Europe and other defined countries. We have retained commercialization rights in Japan and all other countries not subject to the Nycomed and Hospira licenses.

- **ELADUR (TRANSDUR®-Bupivacaine).** Pfizer completed its acquisition of King in February 2011 and as a result has assumed the development and commercialization rights and obligations to ELADUR. In April 2011, we announced top-line results from a Phase II clinical trial conducted by King for the treatment of chronic low back pain. The primary efficacy endpoint for the trial was not met. Complete data analysis is on-going. We and Pfizer are continuing to analyze these data and will work together to determine next steps for ELADUR.

ELADUR is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application. ELADUR demonstrated a positive efficacy trend in a Phase 2a study for post-herpetic neuralgia (PHN); a poster describing this study was presented at the 27th Annual Scientific Meeting of the American Pain Society on May 8, 2008 and is accessible on DURECT's website at www.www.durect.com/wt/durect/page_name/Publications.

- **TRANSDUR-Sufentanil.** We continue 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.

- **ORADUR-ADHD Program.** In July 2010, we and Orient Pharma commenced a Phase I clinical trial in this program evaluating multiple formulations, and in the second quarter of 2011 we and Orient Pharma anticipate commencing a second Phase I study to evaluate additional formulations. ORADUR-ADHD applies our proprietary ORADUR technology to leading active pharmaceutical ingredients for the treatment of attention deficit disorder (ADHD). Under an agreement with Orient Pharma, we are collaborating to perform a clinical development program through a Phase II study intended to produce a data package anticipated to support later stage development of one ADHD drug candidate and subsequent licensing by DURECT. We are responsible for formulation and study design of the pre-defined clinical program, which Orient Pharma will fund and execute.

- **Feasibility Projects and Other Activities.** During the first quarter of 2011, we continued work on several 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.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2011 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 5 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 a specialty pharmaceutical company developing innovative drugs for pain and chronic diseases, with late-stage development programs including REMOXY®, POSIDUR(TM), ELADUR®, and TRANSDUR®-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®, TRANSDUR®, ELADUR®, and DURIN® 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 potential approval and timing of approval of REMOXY by the FDA and subsequent product launch by Pfizer, anticipated completion of enrollment of BESST and receipt of top-line data for POSIDUR, possible licensing transactions relating to TRANSDUR-Sufentanil, future development activities regarding ELADUR, anticipated commencement of a new Phase I trial for ORADUR-ADHD and our other drug candidates and the potential benefits and uses of our drug candidates 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, the risk of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of our drug candidates, the potential failure of our clinical trials to meet their intended endpoints, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and 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, or ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, 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-K on March 3, 2011 under the heading "Risk Factors."

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of March 31, 2011 (unaudited)	As of December 31, 2010 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,830	$ 10,437
Short-term investments	33,541	35,005
Short-term restricted investments	–	66
Accounts receivable	3,816	3,716
Inventories	2,956	2,836
Prepaid expenses and other current assets	2,650	2,785
Total current assets	47,793	54,845
Property and equipment, net	1,752	1,776
Goodwill	6,399	6,399
Intangible assets, net	67	71
Long-term investments	2,674	3,197
Long-term restricted Investments	867	867
Other long-term assets	393	405
Total assets	$ 59,945	$ 67,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 879	$ 981
Accrued liabilities	3,976	6,524
Contract research liability	2,977	2,109
Deferred revenue, current portion	8,086	8,079
Other short-term liabilities	214	216
Total current liabilities	16,132	17,909
Deferred revenue, noncurrent portion	32,829	34,849
Other long-term liabilities	324	315
Stockholders' equity	10,660	14,487
Total liabilities and stockholders' equity	$ 59,945	$ 67,560

(1) Derived from audited financial statements.

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

(unaudited)

	Three months ended March 31,	
	2011	2010
Collaborative research and development and other revenue	$ 5,512	$ 3,816
Product revenue, net	3,092	3,850
Total revenues	8,604	7,666
Operating expenses:		
Cost of revenues (1)	1,401	1,378
Research and development (1)	9,880	9,421
Selling, general and administrative (1)	3,716	3,502
Total operating expenses	14,997	14,301
Loss from operations	(6,393)	(6,635)
Other income (expense):		
Interest and other income	40	11
Interest and other expense	(4)	(2)
Net other income	36	9
Net loss	$ (6,357)	$ (6,626)
Net loss per share, basic and diluted	$ (0.07)	$ (0.08)
Shares used in computing basic and diluted net loss per share	87,270	86,756
(1) Includes stock-based compensation related to the following:		
Cost of revenues	$ 85	$ 84
Research and development	1,127	1,277
Selling, general and administrative	571	669
Total stock-based compensation	$ 1,783	$ 2,030

SOURCE DURECT Corporation