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

CUPERTINO, Calif., Nov. 3, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2011. Total revenues were $8.1 million for the three months ended September 30, 2011 and 2010. Net loss for the three months ended September 30, 2011 was $5.0 million, compared to a net loss of $4.6 million for the same period in 2010.

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

At September 30, 2011, we had cash and investments of $35.1 million, compared to cash and investments of $37.5 million at June 30, 2011 and $49.6 million at December 31, 2010. We have no debt obligations, other than normal liabilities associated with running our business.

“We completed enrollment in our pivotal Phase III trial for POSIDUR(TM) (BESST) in the third quarter, expect to have top-line data in the fourth quarter of this year and, assuming positive data, we expect to submit the New Drug Application in the first half of 2012,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In July, as a culmination of a multi-year feasibility effort with Zogenix, DURECT added an antipsychotic development program to our pipeline. In addition, we continue to support an experienced team at Pfizer in resolving the remaining issues related to REMOXY®.”

Update of Programs:

- **POSIDUR (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot**. During the third quarter of 2011, we dosed the final patient in our U.S. pivotal Phase III clinical study known as BESST (Bupivacaine Effectiveness and Safety in SABER Trial). We dosed 305 patients in BESST, of which 207 were in cohort 3 (the laparoscopically-assisted colectomy cohort in which we hope to show a statistically significant difference in the co-primary efficacy endpoints between POSIDUR and placebo). Cohort 1 (laparotomy) and cohort 2 (laparoscopic cholecystectomy) involved dosing with POSIDUR or commercially available Bupivacaine HCl solution in 48 and 50 patients, respectively. The purpose of Cohorts 1 and 2 is to give additional experience with the use of POSIDUR in a broader group of surgeries and patients; these smaller cohorts were not intended to provide statistical significance with respect to efficacy. We continue to anticipate reporting top-line data in the fourth quarter of 2011, and, assuming positive data, we expect to submit the New Drug Application (NDA) in the first half of 2012.

  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.

- **REMOXY.** On June 23, 2011, Pfizer received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the REMOXY NDA which had been resubmitted in December 2010 by King Pharmaceuticals (acquired by Pfizer in February 2011). The FDA’s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls (CMC) section of the NDA for REMOXY. Pfizer has efforts underway to resolve these issues.

  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.

- **ELADUR (TRANSDUR®-Bupivacaine).** In April 2011, we announced top-line results from a Phase II clinical trial conducted by King Pharmaceuticals for the treatment of chronic low back pain. The primary efficacy endpoint for the trial was not met. We are supporting Pfizer in their evaluation of the ELADUR program.

  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.** We and Orient Pharma have completed two Phase I pharmacokinetic studies with multiple formulations. Based on information from those studies, we are continuing to optimize the formulation. Orient Pharma is our licensee for certain Asian and South Pacific countries.

- **Relday(TM) (Risperidone Program).** In July 2011, we signed a development and license agreement with Zogenix to develop Relday, a product candidate targeting the antipsychotic market. Zogenix will be responsible for the clinical development and commercialization of a proprietary, long-acting (once-monthly) injectable formulation of 0.5 mL of risperidone using DURECT's SABER controlled-release formulation technology in combination with Zogenix's DosePro® needle-free, subcutaneous drug delivery system. DURECT will be responsible for non-clinical, formulation and CMC development activities and will be reimbursed by Zogenix for its research and development efforts on the product. The existing long-acting injectable risperidone product, which achieved $1.5 billion in global net sales in 2010, requires twice-monthly, 2 mL intramuscular injections with a 21 gauge or larger needle. Zogenix expects to initiate clinical studies for Relday in patients with schizophrenia in early 2012. Under the terms of the agreement, Zogenix made an upfront payment of $2.25 million to DURECT in July, with the potential to pay DURECT up to an additional $103 million in future clinical, regulatory and commercial milestone payments based upon successful achievement of certain events. Zogenix will have exclusive global rights to commercialize Relday and will pay DURECT a mid single-digit to low double-digit percentage royalty on net sales.
- **Feasibility Projects and Other Activities.** During the third 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. The Zogenix program, described above, was one such project which has matured into a development and license agreement.
- **Financial Guidance.** Our net cash consumption is influenced by the timing and structure of new corporate collaborations, the achievement of milestones under existing collaborations, and the extent to which we choose to fund unpartnered programs. While we anticipate entering into new collaborations in the future, assuming current funding plans for our R&D programs, no new collaborations and no milestone payments, we currently anticipate our net cash consumption in 2011 will be approximately $19 million and our net cash consumption in 2012 will be approximately $15-17 million.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2011 results will be broadcast live over the internet at4:30 p.m. Eastern Time on November 3 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 the anticipated timing of the receipt of top-line data from BESST, and assuming the data are positive, the submission of the NDA for POSIDUR, anticipated initiation of clinical studies for Relday in early 2012 and potential milestone payments and royalties receivable from Zogenix, the potential benefits and uses of our drug candidates and our expectations as to cash consumption in 2011 and 2012 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-Q on August 5, 2011 under the heading "Risk Factors."

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

	Three months ended	Nine months ended

	September 30,		September 30,	
	2011	2010	2011	2010
Collaborative research and development and other revenue	$ 5,206	$ 5,689	$ 15,906	$ 14,162
Product revenue, net	2,909	2,427	8,646	8,933
Total revenues	8,115	8,116	24,552	23,095
Operating expenses:				
Cost of revenues (1)	1,300	859	3,786	3,098
Research and development (1)	8,452	8,142	27,040	26,767
Selling, general and administrative (1)	3,377	3,806	10,420	10,892
Total operating expenses	13,129	12,807	41,246	40,757
Loss from operations	(5,014)	(4,691)	(16,694)	(17,662)
Other income (expense):				
Interest and other income	31	46	109	105
Interest and other expense	(42)	(2)	(42)	(25)
Net other income (expense)	(11)	44	67	80
Net loss	$ (5,025)	$ (4,647)	$ (16,627)	$ (17,582)
Net loss per share, basic and diluted	$ (0.06)	$ (0.05)	$ (0.19)	$ (0.20)
Shares used in computing basic and diluted net loss per share	87,450	86,892	87,375	86,832
(1) Includes stock-based compensation related to the following:				
Cost of revenues	$ 80	$ 83	$ 247	$ 253
Research and development	1,078	1,151	3,277	3,718
Selling, general and administrative	592	691	1,743	2,023
Total stock-based compensation	$ 1,750	$ 1,925	$ 5,267	$ 5,994

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of September 30, 2011 (unaudited)	As of December 31, 2010 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,031	$ 10,437
Short-term investments	25,428	35,005
Short-term restricted investments	–	66
Accounts receivable	3,045	3,716
Inventories	3,134	2,836
Prepaid expenses and other current assets	1,771	2,785
Total current assets	40,409	54,845
Property and equipment, net	3,412	1,776
Goodwill	6,399	6,399
Intangible assets, net	58	71
Long-term investments	1,799	3,197
Long-term restricted Investments	867	867
Other long-term assets	305	405
Total assets	$ 53,249	$ 67,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,243	$ 981
Accrued liabilities	5,147	6,524
Contract research liability	2,360	2,109
Deferred revenue, current portion	7,372	8,079
Other short-term liabilities	280	216
Total current liabilities	16,402	17,909
Deferred revenue, noncurrent portion	31,932	34,849
Other long-term liabilities	796	315
Stockholders' equity	4,119	14,487
Total liabilities and stockholders' equity	$ 53,249	$ 67,560

(1) Derived from audited financial statements.

SOURCE DURECT Corporation