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

CUPERTINO, Calif., Aug. 4, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months endedJune 30, 2011. Total revenues increased to $7.8 million for the three months ended June 30, 2011 from $7.3 million for the three months ended June 30, 2010. Net loss for the three months ended June 30, 2011 was $5.2 million, compared to a net loss of $6.3 million for the same period in 2010.

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

At June 30, 2011, we had cash and investments of $37.5 million, compared to cash and investments of $41.9 million at March 31, 2011 and $49.6 million at December 31, 2010. We have no debt obligations, other than normal liabilities associated with running our business.

“We are supporting Pfizer in resolving the remaining issues related to REMOXY® and appreciate the experienced team Pfizer has dedicated to these efforts,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We are 11 patients away from completing enrollment in our pivotal Phase III trial for POSIDUR(TM) (BESST), and we expect to have top-line data in the fourth quarter of this year. In July, as a culmination of a multi-year feasibility effort between Zogenix and us, we added a new antipsychotic development program to our pipeline.”

Update of Programs:

- **REMOXY.** On June 23, 2011, Pfizer received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the REMOXY New Drug Application (NDA) which had been resubmitted in December 2010. 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 is working to evaluate the issues described in the Complete Response Letter, has efforts underway to resolve these issues and plans to have further discussions with the FDA about them. Resolution of these issues and potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

  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.

- **POSIDUR (SABER(TM)-Bupivacaine) Post-Operative Pain Relief Depot**. During the second quarter of 2011, patient enrollment continued in our U.S. pivotal Phase III clinical study known as BESST (Bupivacaine Effectiveness and Safety in SABER Trial). As of August 3, we had dosed 293 patients out of our target of 304. At our current enrollment rate, we expect to complete enrollment in approximately a month. We continue to anticipate reporting top-line data in the fourth quarter 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 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 Pharmaceuticals (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. 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.** In recent months, we have had discussions with the FDA and regulatory agencies in several major European countries to better understand development requirements for U.S. and European approval in furtherance of our development plans for 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 the second quarter of 2011, we and Orient Pharma completed a Phase I pharmacokinetic study with multiple formulations. We are continuing to optimize the formulation and are planning next steps in our ORADUR-ADHD program.

- **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 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 second 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.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2011 results will be broadcast live over the internet at4:30 p.m. Eastern Time on August 4 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 Pfizer's on-going review and interactions with FDA regarding approval of the REMOXY NDA and the potential of resolving all outstanding regulatory concerns regarding REMOXY, anticipated completion of enrollment of BESST and receipt of top-line data for POSIDUR, future development activities and possible licensing transactions relating to TRANSDUR-Sufentanil, future development activities regarding ELADUR, anticipated optimization of a formulation for ORADUR-ADHD and next steps in that program, anticipated initiation of clinical studies for Relday in early 2012 and potential milestone payments and royalties receivable from Zogenix, 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-Q on May 4, 2011 under the heading "Risk Factors."

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

	Three months ended June 30,	Six months ended June 30,

	2011	2010	2011	2010
Collaborative research and development and other revenue	$ 5,188	$ 4,657	$ 10,700	$ 8,473
Product revenue, net	2,645	2,656	5,737	6,506
Total revenues	7,833	7,313	16,437	14,979
Operating expenses:				
Cost of revenues (1)	1,085	861	2,486	2,239
Research and development (1)	8,708	9,204	18,588	18,625
Selling, general and administrative (1)	3,327	3,584	7,043	7,086
Total operating expenses	13,120	13,649	28,117	27,950
Loss from operations	(5,287)	(6,336)	(11,680)	(12,971)
Other income (expense):				
Interest and other income	43	48	83	59
Interest and other expense	(1)	(21)	(5)	(23)
Net other income	42	27	78	36
Net loss	$ (5,245)	$ (6,309)	$ (11,602)	$ (12,935)
Net loss per share, basic and diluted	$ (0.06)	$ (0.07)	$ (0.13)	$ (0.15)
Shares used in computing basic and diluted net loss per share	87,404	86,845	87,338	86,801
(1) Includes stock-based compensation related to the following:				
Cost of revenues	$ 82	$ 86	$ 167	$ 170
Research and development	1,072	1,290	2,199	2,567
Selling, general and administrative	580	663	1,151	1,332
Total stock-based compensation	$ 1,734	$ 2,039	$ 3,517	$ 4,069

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2011 (unaudited)	December 31, 2010 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,486	$ 10,437
Short-term investments	29,247	35,005
Short-term restricted investments	–	66
Accounts receivable	3,290	3,716
Inventories	3,265	2,836
Prepaid expenses and other current assets	1,251	2,785
Total current assets	42,539	54,845
Property and equipment, net	2,204	1,776
Goodwill	6,399	6,399
Intangible assets, net	62	71
Long-term investments	1,924	3,197
Long-term restricted Investments	867	867
Other long-term assets	349	405
Total assets	$ 54,344	$ 67,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,001	$ 981
Accrued liabilities	4,303	6,524
Contract research liability	2,157	2,109
Deferred revenue, current portion	8,079	8,079
Other short-term liabilities	229	216
Total current liabilities	15,769	17,909
Deferred revenue, noncurrent portion	30,809	34,849
Other long-term liabilities	357	315
Stockholders' equity	7,409	14,487
Total liabilities and stockholders' equity	$ 54,344	$ 67,560

(1) Derived from audited financial statements.

SOURCE DURECT Corporation