DURECT Corporation Announces Fourth Quarter 2012 Financial Results and Update of Programs

CUPERTINO, Calif., Feb. 28, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended December 31, 2012. Total revenues were $3.3 million for the three months ended December 31, 2012 as compared to $8.9 million for the three months ended December 31, 2011. Net loss was $5.5 million for the three months ended December 31, 2012 as compared to a net loss of $2.1 million for the same period in 2011.

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

Total revenues were $53.1 million and net income was $16.2 million for the year ended December 31, 2012; these figures include the accelerated recognition in the first quarter of 2012 of $35.4 million in deferred revenue associated with upfront fees previously received under terminated collaboration agreements. This $35.4 million in revenue was non-recurring and had no cash flow impact for the year. Excluding the accelerated recognition of deferred revenue, DURECT's reported revenues would have been $17.7 million for the year ended December 31, 2012 (as compared to $25.9 million for the same period in 2011 excluding the recognition of deferred revenue associated with the agreements terminated in 2012) and reported net loss would have been $19.2 million for the year ended December 31, 2012 (as compared to a net loss of $26.3 million for the same period in 2011 excluding the recognition of deferred revenue associated with the agreements terminated in 2012).

At December 31, 2012, we had cash and investments of $28.9 million, compared to cash and investments of $30.8 million at December 31, 2011. We have no debt obligations, other than normal liabilities associated with running our business.

"We are in the final stages of preparing a new drug application for POSIDUR™, which we expect to submit to the FDA near the end of the first quarter of 2013," stated James E. Brown, D.V.M., President and CEO of DURECT. "Communications with Pfizer indicate that they intend to meet with the FDA as planned in late March to discuss their proposed resubmission plan for REMOXY®. We also are pleased that Zogenix recently reported positive Phase 1 clinical trial results for Relday™ and has quickly extended that trial at a higher dose."

In 2013, we look forward to:

- Pfizer conducting a meeting with the FDA to discuss the REMOXY resubmission
- Submitting the POSIDUR NDA near the end of Q1 2013
- Supporting Zogenix as they extend a Phase I study with Relday
- Selecting a formulation based on our Phase I studies to take forward in our ORADUR®-ADHD program
- Potentially entering into additional feasibility studies and collaborations
- Continuing to add to our patent portfolio

Highlights for DURECT in Fiscal Year 2012 and Major Potential Milestones over the Next 12-18 Months:

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Pfizer has efforts underway to resolve the issues raised in the REMOXY Complete Response Letter, which are primarily manufacturing. Pfizer is targeting a meeting with the FDA in late March to discuss their proposed resubmission plan for REMOXY. Based on feedback Pfizer receives from the FDA at the meeting, Pfizer will subsequently determine the next steps and/or required timing to respond to the Complete Response Letter.
  REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time. Based on DURECT's ORADUR technology, which is covered by issued patents and pending patent applications owned by us, REMOXY is designed to discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse.

- **POSIDUR(SABER®-Bupivacaine) Post-Operative Pain Relief Depot**. Following our pre-NDA communications during the summer of 2012 with the FDA regarding POSIDUR, we intend to submit a new drug application (NDA) under 505(b)(2) with the FDA near the end of the first quarter of 2013.

  POSIDUR is our investigational 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. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights.

- **Transdermal Development Candidates.** DURECT has two transdermal products that are in mid- to late-stage development with features that may be superior to currently available patches. TRANSDUR®-Sufentanil is our proprietary transdermal patch intended to deliver sufentanil to chronic pain sufferers for a period of up to 7 days from a single application; this compares favorably against existing fentanyl patches which are substantially larger and typically effective for 2-3 days. ELADUR®, for topical neuropathic conditions such as post-herpetic neuralgia (PHN), is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application; existing lidocaine patches for this condition can be worn for 12 hours with a rest period of 12 hours during which time many patients experience breakthrough pain. We are in discussions with potential partners regarding licensing development and commercialization rights to these two transdermal programs for which we hold worldwide rights.
- **ORADUR-ADHD Program.** We are developing a drug candidate (ORADUR-ADHD) based on DURECT's ORADUR Technology for the treatment of Attention Deficit Hyperactivity Disorder. This drug candidate is intended to provide once-a-day dosing with added tamper resistant characteristics to address common methods of abuse and misuse of these types of drugs. We and Orient Pharma have completed several Phase I pharmacokinetic studies with multiple formulations, and we are continuing to optimize our lead formulations. Orient Pharma is our licensee for certain Asian and South Pacific countries, while we retain the rights to the rest of the world.
- **Relday (Risperidone Program).** In July 2011, we signed a development and license agreement with Zogenix to develop Relday, a product candidate targeting the antipsychotic market. In January 2013, Zogenix announced positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday. According to Zogenix, adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products. The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix has extended the study to include a 100 mg dose of the same formulation. The addition of this dose arm to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Zogenix expects to complete the extension of the Phase 1 clinical trial during the second quarter of 2013.

  Relday is a proprietary, long-acting (once-monthly) subcutaneous injectable formulation of risperidone using DURECT's SABER controlled-release formulation technology. An existing long-acting injectable risperidone product, which achieved $1.4 billion in global net sales in 2012, requires twice-monthly, intramuscular injections and drug reconstitution prior to use.

- **Feasibility Projects and Other Activities.** During the fourth quarter of 2012, we continued work on several feasibility projects and signed new 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.
- **Patent Issuances.** In 2012, we had multiple important patents issue in the U.S. and other important commercial markets. In addition to these issuances, we continue to file new applications protecting our technologies and programs, and are pursuing existing applications which may extend the patent life of several key programs. Reflecting key issuances since January 1, 2012, our patent portfolio now includes:
  - REMOXY. In the U.S., REMOXY is now covered by four patent families. Two patent families include granted patents expiring in at least 2015 and 2025, respectively. The later expiring of these two patent families includes five granted patents. In Europe, REMOXY is covered by two granted patents expiring in at least 2016 and 2023, respectively.
  - POSIDUR. In the U.S., POSIDUR is now covered by two patent families, which include granted patents expiring in at least 2015 and 2025, respectively. In Europe, POSIDUR is covered by two granted patents expiring in at least 2016 and 2025, respectively.
  - ELADUR. In the U.S., we received issuance of a patent expiring in 2031 and in Europe we also received issuance of a patent expiring in at least 2027.
  - TRANSDUR-Sufentanil. In the U.S., we received issuance of three patents with coverage until at least 2025 and in Europe, we also received issuance of a patent with coverage until at least 2025.

- **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 without funding from new collaborations or milestone payments, we currently anticipate our net cash consumption in 2013 will be approximately $14-16 million.
- **Business Development Activities.** We have multiple programs that may potentially be licensed over the next 12-18 months. These include POSIDUR, TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD (territories outside certain Asian and South Pacific markets), as well as various other programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss fourth quarter 2012 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on February 28 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™, 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™, SABER®, ORADUR®, TRANSDUR® and ELADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR, TRANSDUR-Sufentanil and Relday 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 regulatory meetings and submissions for REMOXY and POSIDUR, anticipated clinical trials (including timing and results) for Relday and our other drug candidates, projected cash consumption, the potential benefits and uses of our drug candidates, collaborations with third parties and potential business development activities 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 that Pfizer will discontinue development of REMOXY, the risk of adverse decisions by regulatory agencies, including rejection of meeting requests, requests for additional information or product non-approval or non-acceptance of our POSIDUR or other NDA submissions, 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 risks related to our (and our third party collaborators where applicable) ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of product candidates, manufacture and commercialize product candidates, obtain marketplace acceptance of product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on November 6, 2012 under the heading "Risk Factors."

DURECT CORPORATION

STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2012	2011	2012	2011[1]
Collaborative research and development and other revenue	$ 813	$ 6,454	$42,494	$ 22,360
Product revenue, net	2,449	2,481	10,576	11,127
Total revenues	3,262	8,935	53,070	33,487

Operating expenses:					
	Cost of product revenues	1,038	927	4,654	4,713
	Research and development	4,904	7,013	20,265	34,053
	Selling, general and administrative	2,911	3,154	12,095	13,574
Total operating expenses		8,853	11,094	37,014	52,340
Income (loss) from operations		(5,591)	(2,159)	16,056	(18,853)
Other income (expense):					
	Interest and other income	95	25	151	134
	Interest and other expense	(2)	(4)	(7)	(46)
Net other income		93	21	144	88
Net Income (loss)		$(5,498)	$(2,138)	$16,200	$(18,765)
Net income (loss) per share					
	Basic	$ (0.06)	$ (0.02)	$ 0.18	$ (0.21)
	Diluted	$ (0.06)	$ (0.02)	$ 0.18	$ (0.21)
Weighted-average shares used in computing net income (loss) per share					
	Basic	90,881	87,514	88,433	87,410
	Diluted	90,881	87,514	88,589	87,410
Total comprehensive income (loss)		$(5,498)	$(2,144)	$16,201	$(18,766)

(1) Derived from audited financial statements.

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of December 31, 2012 (unaudited)	As of December 31, 2011[(1)]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,195	$ 8,896
Short-term investments	17,337	19,535
Short-term restricted investments	–	367
Accounts receivable	2,166	3,448
Inventories	3,399	3,252
Prepaid expenses and other current assets	2,258	1,803
Total current assets	36,355	37,301
Property and equipment, net	2,457	3,124
Goodwill	6,399	6,399
Intangible assets, net	36	53
Long-term investments	–	1,530
Long-term restricted Investments	400	501
Other long-term assets	288	288
Total assets	$ 45,935	$ 49,196
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,785	$ 1,274
Accrued liabilities	3,997	4,884
Contract research liability	483	1,361
Deferred revenue, current portion	662	7,372
Total current liabilities	6,927	14,891
Deferred revenue, noncurrent portion	1,480	30,090
Other long-term liabilities	1,197	738
Stockholders' equity	36,331	3,477
Total liabilities and stockholders' equity	$ 45,935	$ 49,196

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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