DURECT Corporation Announces Fourth Quarter and Year End 2010 Financial Results

Progress in product development, business development, and strong financial results highlight 2010

CUPERTINO, CA, March 2, 2011/PRNewswire-FirstCall/ -- DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2010. Total revenues were $8.5 million for the three months ended December 31, 2010, up from $4.9 million for the three months ended December 31, 2009. Net loss for the three months ended December 31, 2010 was $5.3 million, down from a net loss of $8.6 million for the same period in 2009.

For the fiscal year ended December 31, 2010, total revenues were $31.6 million, up from $24.5 million for the same period in 2009. Net loss for the year ended December 31, 2010 was $22.9 million, down from a net loss of $30.3 million for the same period in 2009.

At December 31, 2010, we had cash and investments of $49.6 million, compared to cash and investments of $41.6 million at December 31, 2009. We have no debt obligations, other than normal liabilities associated with running our business.

"2010 was a strong year for DURECT in product development and business development, with the establishment of a major collaboration around POSIDUR™ that enabled us to generate positive cash flow for the year," stated James E. Brown, D.V.M., President and CEO of DURECT. "We look forward to the potential approval of REMOXY® in 2011 and subsequent launch by Pfizer."

Key milestones met in 2010 include:

- Resubmission of the REMOXY NDA by King Pharmaceuticals, with an anticipated PDUFA goal date of June 23, 2011
- Initiation of and continued enrollment in the POSIDUR U.S. pivotal Phase III trial
- Establishment of Hospira as POSIDUR's development and commercialization partner for the U.S. and Canada
- Commencement of a Phase IIb study for ELADUR® by King
- Initiation of Phase I in our ORADUR®-ADHD program

In 2011, we look forward to:

- Potential approval of REMOXY by the FDA and subsequent launch by Pfizer
- Completion of the POSIDUR Phase III study
- Reporting of Phase IIb results for ELADUR
- Advancing our ORADUR-ADHD and other research and development programs
- Potentially entering into additional collaborations

Highlights for DURECT in Fiscal Year 2010 and Major Potential Milestones over the Next 12-18 Months:

- **REMOXY.** We are looking forward to the anticipated June 23, 2011 PDUFA goal date. In December 2010, King resubmitted the New Drug Application (NDA) for REMOXY to the U.S. Food and Drug Administration (FDA) in response to a Complete Response Letter received by Pain Therapeutics in December 2008. In July 2009, King met with the FDA to discuss the Complete Response Letter. Pfizer completed its acquisition of King in February 2011 and as a result has assumed the development and commercialization rights and obligations to REMOXY and to the three other licensed ORADUR-based opioid drug candidates (hydrocodone, hydromorphone and oxymorphone).

  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™-Bupivacaine) Post-Operative Pain Relief Depot**. In 2010 and early 2011, Nycomed completed two Phase II studies in Europe, one in hysterectomy and another in shoulder surgery. In February 2011, we and Nycomed amended our agreement such that 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.

  During 2010, we enrolled 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 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 2010, King Pharmaceuticals initiated a Phase IIb trial evaluating the safety and efficacy of ELADUR in approximately 260 patients with chronic low back pain. We expect to receive top-line results from that study in the first half of 2011.

  ELADUR is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application.

- **TRANSDUR-Sufentanil.** During 2010, we conducted new market research on this product opportunity and have been incorporating that information in developing revised potential development plans for TRANSDUR-Sufentanil. 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.

- **ORADUR-ADHD Program.** In July 2010, we commenced a Phase I clinical trial in this program evaluating multiple 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 2010, we conducted 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. During 2011, we anticipate establishing and commencing additional feasibility projects with biotechnology and pharmaceutical company collaborators utilizing our drug delivery technologies.

  In February 2011, we announced that our collaborator, CreoSalus, had launched commercial sales of SucroMate™ Equine, an FDA approved product which is an injectable animal health drug utilizing DURECT's SABER technology to deliver the peptide deslorelin. DURECT will receive a royalty on net sales of this product and will supply one of the key excipients in the product. Although this product represents a modest revenue opportunity for DURECT by itself, the SABER technology is the basis for our POSIDUR program currently in a pivotal Phase III clinical trial as well as for multiple on-going feasibility projects seeking to deliver proteins and peptides for periods of up to one month from a single injection.

- **Financial Guidance.** Our net cash consumption is heavily influenced by the timing and structure of new corporate collaborations, as well as the achievement of milestones under existing collaborations. While we anticipate entering into new collaborations in 2011 and beyond, assuming no new collaborations, no milestone or royalty payments and aggressive funding of our R&D programs, many of which are in clinical development, we anticipate our net cash consumption in 2011 will be approximately $23-27 million.

- **Business Development Activities.** We have multiple programs that may potentially be partnered over the next 12-18 months. These include TRANSDUR-Sufentanil worldwide rights, POSIDUR for Japan, ORADUR-ADHD, as well as various internal programs which we have not described publicly in detail.

Earnings Conference Call
A live audio webcast of a conference call to discuss 2010 results will be broadcast over the internet at 4:30 p.m. Eastern Time on March 2 and is available by accessing DURECT's homepage at 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.durect.com.

NOTE: POSIDUR™, SABER™, 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, our anticipated net cash consumption, anticipated clinical trials (including timing and results) for POSIDUR, TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD and our other drug candidates, 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, 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 November 4, 2010 under the heading "Risk Factors."

DURECT CORPORATION

STATEMENT OF OPERATIONS DATA
(in thousands, except per share amounts)
(Unaudited)

	Three months ended December 31,		Year ended December 31,	
	2010	2009	2010	2009 (1)
Collaborative research and development and other revenue	$ 5,929	$ 2,802	$ 20,091	$ 12,347
Product revenue, net	2,567	2,076	11,500	12,113
Total revenues	8,496	4,878	31,591	24,460
Operating expenses:				
Cost of revenues [(2)]	1,177	816	4,275	5,311
Research and development [(2)]	9,447	9,267	36,214	34,801
Selling, general and administrative [(2)]	4,045	3,432	14,937	15,020
Total operating expenses	14,669	13,515	55,426	55,132
Loss from operations	(6,173)	(8,637)	(23,835)	(30,672)
Other income (expense):				
Interest and other income	858	53	943	420
Interest and other expense	(1)	(5)	(6)	(36)
Net other income	857	48	937	384
Net loss	$ (5,316)	$ (8,589)	$ (22,898)	$ (30,288)
Net loss per share, basic and diluted	$ (0.06)	$ (0.10)	$ (0.26)	$ (0.36)
Shares used in computing basic and diluted net loss per share	86,976	86,720	86,868	83,427

(1) Derived from audited financial statements.

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

Cost of revenues	$ 88	$ 147	$ 341	$ 433
Research and development	1,223	1,886	4,941	7,159
Selling, general and administrative	497	1,018	2,520	3,838
Total stock-based compensation	$ 1,808	$ 3,051	$ 7,802	$ 11,430

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of December 31, 2010 (unaudited)	As of December 31, 2009 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,437	$ 8,287
Short-term investments	35,005	32,834
Short-term restricted investments	66	-
Accounts receivable	3,716	1,700
Inventories	2,836	2,799
Prepaid expenses and other current assets	2,785	1,433
Total current assets	54,845	47,053
Property and equipment, net	1,776	3,808
Goodwill	6,399	6,399
Intangible assets, net	71	108
Long-term investments	3,197	-
Long-term restricted Investments	867	431
Other long-term assets	405	352
Total assets	$ 67,560	$ 58,151
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 981	$ 1,019
Accrued liabilities	6,524	5,337
Contract research liability	2,109	990
Deferred revenue, current portion	8,079	4,703
Other short-term liabilities	216	208
Total current liabilities	17,909	12,257
Deferred revenue, noncurrent portion	34,849	17,543
Other long-term liabilities	315	508
Stockholders' equity	14,487	27,843
Total liabilities and stockholders' equity	$ 67,560	$ 58,151

(1) Derived from audited financial statements.

SOURCE: DURECT Corporation
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