DURECT Corporation Announces Third Quarter 2010 Financial Results

CUPERTINO, Calif., Nov. 3, 2010 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2010. Total revenues were $8.1 million for the three months ended September 30, 2010 compared to $8.4 million for the three months ended September 30, 2009; revenues in the 2009 period included $3.0 million recognized from the sale of certain excipients used in REMOXY(R) to King Pharmaceuticals in prior periods. Net loss for the three months ended September 30, 2010 was $4.6 million, compared to a net loss of $5.5 million for the same period in 2009.

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At September 30, 2010, we had cash and investments of $53.0 million, compared to cash and investments of $41.6 million at December 31, 2009.

“Our pipeline of product candidates continued to advance during the third quarter while we maintained a modest burn rate,” stated James E. Brown, D.V.M., President and CEO of DURECT. “King Pharmaceuticals is preparing the NDA resubmission for REMOXY by year-end. King continues to enroll chronic low back pain patients in a Phase IIb clinical study of our proprietary bupivacaine patch, ELADUR(TM); we currently anticipate receiving top-line data from that study in the first half of 2011. Should Pfizer complete its acquisition of King, we believe that Pfizer will bring added development and commercialization strength to REMOXY, the other ORADUR-based opioids in our collaboration as well as ELADUR. During the quarter, we also continued to enroll patients in BESST, our pivotal U.S. Phase III clinical study for POSIDUR(TM). Our cash burn rate in the quarter declined to $4.2 million from $6.1 million in the previous quarter, reflecting the first full quarter of our collaboration with Hospira covering the development and commercialization of POSIDUR in the U.S. and Canada, and we anticipate that we will be cash flow positive for all of 2010 by approximately $6 million.”

Business Highlights:

- **REMOXY.** Our understanding is that King anticipates that in the fourth quarter of 2010 it will resubmit the NDA for REMOXY intended to address all FDA comments in the Complete Response Letter. In July 2009, King met with the FDA to discuss the Complete Response Letter received in December 2008 regarding the REMOXY NDA. Assuming Pfizer completes its acquisition of King, Pfizer will assume 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(R) 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.** In June 2010, we entered into an agreement with Hospira covering the development and commercialization of POSIDUR in the U.S. and Canada. Under terms of the agreement, Hospira made an upfront payment to us of $27.5 million, with the potential for up to an additional $185 million in performance based milestone payments based on the successful development, approval and commercialization of POSIDUR. For the U.S. and Canada, the two companies will jointly direct and equally fund the remaining development costs for POSIDUR, while Hospira will have exclusive commercialization rights with sole funding responsibility for commercialization activities. In addition, if commercialized, Hospira will pay DURECT a royalty on product sales.

  In the third quarter of 2010, we continued to enroll 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(TM)-Bupivacaine).** In October 2008, worldwide rights to this program were licensed to Alpharma, which was acquired by King Pharmaceuticals in December 2008. In April 2010, King Pharmaceuticals initiated a Phase IIb trial evaluating the safety and efficacy of ELADUR in patients with chronic low back pain. King expects to enroll approximately 260 patients in this study and we expect to receive top-line results from that study in the first half of 2011. Assuming Pfizer completes its acquisition of King, Pfizer will assume the development and commercialization rights and obligations to ELADUR.

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

- **TRANSDUR-Sufentanil.** In February 2009, a successful end-of-Phase II meeting with the FDA was conducted for this program outlining a potential regulatory pathway for the Phase III program and NDA submission. During 2009, we transitioned the program back to our control. 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 with multiple formulations. ORADUR-ADHD applies our proprietary ORADUR technology to a leading active pharmaceutical ingredient 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 that will support later stage development of the 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.
- **Therapeutic Discovery Tax Grant.** In October 2010, DURECT was notified that we have been awarded grants totaling $733,438 under the Patient Protection and Affordable Care Act of 2010 for three qualifying therapeutic discovery projects; we expect to receive this funding in the fourth quarter of 2010.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2010 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 3 and is available by accessing DURECT's homepage at\durectfile1 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 other chronic diseases, with late-stage development programs including REMOXY, POSIDUR, ELADUR, and TRANSDUR-Sufentanil. DURECT's proprietaryoral, 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 http://www.www.durect.com/.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(TM), ELADUR(TM), and DURIN(TM) 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 our projected financial results including annual cash burn, the anticipated resubmission of the REMOXY NDA, the potential acquisition of King Pharmaceuticals by Pfizer, our U.S. pivotal Phase III clinical trial (BESST) for POSIDUR including the anticipated timing of completion of the trial and patient enrollment numbers, potential milestone payments and royalties receivable from Hospira, Phase IIb trial for ELADUR including anticipated patient enrollment numbers and timing thereof, our intention to enter into collaborations with respect to TRANSDUR-Sufentanil and our ORADUR-ADHD Phase I trial, 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, delays and additional costs due to requirements imposed by regulatory agencies on our drug candidates, unexpected results and adverse events from clinical trials for our drug candidates, our failure to achieve the performance milestones or commercial sales that trigger the referenced payments or royalties under our collaborative agreements, our (and that of our third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to development activities and products, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced drug candidates, consummate collaborative agreements relating to our drug candidates and technologies, manufacture and commercialize the referenced drug candidates, obtain marketplace acceptance of the referenced drug candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on August 5, 2010 under the heading "Risk Factors."

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

	Three months ended September 30,	Nine months ended September 30,

	2010	2009	2010	2009
Collaborative research and development and other revenue	$ 5,689	$ 3,027	$ 14,162	$ 9,545
Product revenue, net	2,427	5,351	8,933	10,037
Total revenues	8,116	8,378	23,095	19,582
Operating expenses:				
Cost of product revenues (1)	859	2,834	3,098	4,495
Research and development (1)	8,142	7,598	26,767	25,534
Selling, general and administrative (1)	3,806	3,554	10,892	11,588
Total operating expenses	12,807	13,986	40,757	41,617
Loss from operations	(4,691)	(5,608)	(17,662)	(22,035)
Other income (expense):				
Interest and other income	46	82	105	367
Interest and other expense	(2)	(9)	(25)	(31)
Net other income	44	73	80	336
Net loss	$ (4,647)	$ (5,535)	$ (17,582)	$ (21,699)
Net loss per share, basic and diluted	$ (0.05)	$ (0.07)	$ (0.20)	$ (0.26)
Shares used in computing basic and diluted net loss per share	86,892	82,781	86,832	82,317
(1) Includes stock-based compensation related to the following:				
Cost of product revenues	$ 83	$ 91	$ 253	$ 286
Research and development	1,151	1,665	3,718	5,273
Selling, general and administrative	691	785	2,023	2,820
Total stock-based compensation	$ 1,925	$ 2,541	$ 5,994	$ 8,379

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2010 (unaudited)	As of December 31, 2009 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,138	$ 8,287
Short-term investments	34,518	32,834
Short-term restricted investments	66	–
Accounts receivable	3,311	1,700
Inventories	2,964	2,799
Prepaid expenses and other current assets	1,676	1,433
Total current assets	54,673	47,053
Property and equipment, net	2,114	3,808
Goodwill	6,399	6,399
Intangible assets, net	76	108
Long-term investments	5,908	–
Long-term restricted Investments	367	431
Other long-term assets	288	352
Total assets	$ 69,825	$ 58,151
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 599	$ 1,019
Accrued liabilities	4,709	5,337
Contract research liability	1,310	990
Deferred revenue, current portion	8,079	4,703
Other short-term liabilities	218	208
Total current liabilities	14,915	12,257
Deferred revenue, noncurrent portion	36,868	17,543
Other long-term liabilities	344	508
Stockholders' equity	17,698	27,843
Total liabilities and stockholders' equity	$ 69,825	$ 58,151

(1) Derived from audited financial statements.

SOURCE DURECT Corporation