DURECT Corporation Announces Third Quarter 2009 Financial Results

CUPERTINO, Calif., Oct 29, 2009 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2009. Total revenues were $8.4 million for the three months ended September 30, 2009, compared to $6.6 million for the same period in 2008; revenues in the 2009 period included $3.0 million related to the sale of certain excipients used in REMOXY(R) to King Pharmaceuticals in 2008 and the first quarter of 2009, all of which was recognized upon the execution of the long term supply agreement between us and King in the third quarter of 2009. Net loss for the three months ended September 30, 2009 was $5.5 million, compared to a net loss of $9.2 million for the same period in 2008.

(Logo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO)

At September 30, 2009, DURECT had cash and investments of $47.2 million, compared to cash and investments of $52.7 million at December 31, 2008; these figures include restricted investments of $0.8 million at September 30, 2009 and $1.0 million at December 31, 2008.

“Since our last earnings report, we have continued to advance our development programs and business activities, including completing enrollment in our POSIDUR(TM) Phase II shoulder study, entering into a new collaboration with Orient Pharma that will allow us to generate Phase II data for a new drug candidate for the Attention Deficit Hyperactivity Disorder market (ORADUR(R)-ADHD) and a long term excipient supply agreement with King Pharmaceuticals with respect to REMOXY,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, we enhanced our cash position with a $10 million sale of common stock to affiliates of Venrock, a highly respected institutional investor.”

Recent Highlights:

— Remoxy. According to a King Pharmaceuticals / Pain Therapeutics press release, King anticipates the resubmission of the NDA for REMOXY intended to address all FDA comments in the Complete Response Letter could occur mid-year 2010. King has stated that it remains committed to the development and commercialization of REMOXY and looks forward to working closely with the FDA toward approval of the product. During the third quarter, DURECT and King signed an exclusive long term excipient supply agreement with respect to REMOXY. This agreement stipulates the terms and conditions under which DURECT will supply to King, based on DURECT’s manufacturing cost plus a specified percentage mark-up, two key excipients used in the manufacture of REMOXY.

REMOXY is an investigational 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(TM) (SABER(TM)-Bupivacaine). DURECT recently completed enrollment in our Phase IIb clinical study in shoulder surgery of approximately 60 patients and we expect to have top line data analysis completed in December. In addition, Nycomed continues enrollment in a Phase IIb study in hysterectomy patients and a Phase IIb study in shoulder surgery patients. At the American College of Surgeons 95th Annual Clinical Congress on October 12, 2009, we presented a scientific poster regarding our Phase IIb hernia study; this poster can be accessed through www.www.durect.com under “About DURECT” and “Publications.” We are in active discussions with multiple potential partners regarding

licensing of the U.S./Canadian and Asian rights to this program.

POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER technology intended to deliver bupivacaine to provide up to three days of pain relief after surgery. POSIDUR is licensed to Nycomed for commercialization in Europe and select other countries, and we have retained commercialization rights in the US, Canada and Asia.

— ELADUR(TM) (TRANSDUR(TM)-Bupivacaine). In October 2008, worldwide rights to this program were licensed to Alpharma, which was acquired by King Pharmaceuticals in December 2008. We continue to interact with the King team on details associated with next steps in the clinical program, which King expects to initiate in the first half of next year.

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

— TRANSDUR-Sufentanil. A successful end-of-Phase II meeting with the FDA has been conducted for this program that laid out a potential regulatory pathway for the Phase III program and NDA submission. We are in active discussions with multiple 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 provide sufentanil to chronic pain sufferers for a period of up to seven days from a single application.

— License Agreement for ADHD Drug Candidate. During the third quarter, we signed a development and license agreement with Orient Pharma Co., Ltd. under which DURECT has granted to Orient Pharma development and commercialization rights in selected Asian and South Pacific countries to a drug candidate based on DURECT's ORADUR Technology and one specified active pharmaceutical ingredient for the treatment of attention deficit hyperactivity disorder (ADHD). This drug candidate (ORADUR-ADHD) 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. North American, European, Japanese and select other countries' rights to this drug candidate are retained by DURECT. Under this agreement, the parties will collaborate 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 by DURECT as well as Orient Pharma in their respective territories. DURECT will be responsible for formulation and study design of the pre-defined clinical program which Orient Pharma will fund and execute.

— Financing. In September, DURECT entered into a privately negotiated transaction to sell 4,444,444 shares of common stock to affiliates of Venrock at a price of $2.25 per share, raising proceeds to DURECT of approximately $10 million.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2009 results will be broadcast over the internet at 4:30 p.m. Eastern Time on October 29 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 an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-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(R), TRANSDUR(TM), and ELADUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR, TRANSDUR-Sufentanil and ORADUR-ADHD are drug candidates under development and have not been approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding plans by King Pharmaceuticals for resubmission of the REMOXY NDA in mid-2010 and their belief that this resubmission will address all FDA comments in the Complete Response Letter, the potential of FDA approving the REMOXY NDA, the expectation that we will have top line data from our Phase IIb shoulder study in December, the expectation that King will commence additional clinical studies in the first half of next year with ELADUR, our plan to generate Phase II data with our ORADUR-ADHD program, our possible licensing of development and commercialization rights to POSIDUR and TRANSDUR-Sufentanil to third parties, and potential agreements with third parties to license the development and commercialization rights to our product 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 potential that the REMOXY NDA resubmission may take longer to achieve than expected and may not adequately address all of FDA's concerns, the potential that FDA may not grant regulatory approval of REMOXY, failure of our clinical trials to produce intended results, possible adverse events associated with the use of our drug candidates, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of our drug candidates, 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, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, consummate collaborative agreements relating to our product candidates and technologies, 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 filed on August 4, 2009 under the heading "Risk Factors."

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

	Three months ended September 30,		Year ended September 30,	
	2009	2008	2009	2008
Collaborative research and development revenue	$3,027	$4,341	$9,378	$12,477

Product revenue, net	5,351	2,293	10,037	6,898
Total revenues	8,378	6,634	19,415	19,375
Operating expenses:				
Cost of revenues (1)	2,834	870	4,495	2,674
Research and development (1)	7,598	11,423	25,367	30,955
Selling, general and administrative (1)	3,554	3,837	11,588	11,813
Total operating expenses	13,986	16,130	41,450	45,442
Loss from operations	(5,608)	(9,496)	(22,035)	(26,067)
Other income (expense):				
Interest and other income	82	349	367	1,285
Interest expense	(9)	(14)	(31)	(773)
Net other income	73	335	336	512
Net loss	$(5,535)	$(9,161)	$(21,699)	$(25,555)
Net loss per share, basic and diluted	$(0.07)	$(0.11)	$(0.26)	$(0.33)
Shares used in computing basic and diluted net loss per share	82,781	81,779	82,317	77,124

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

Cost of revenues	$91	$44	$286	$110
Research and development	1,665	1,300	5,273	4,267
Selling, general and administrative	785	619	2,820	2,068
Total stock-based compensation	$2,541	$1,963	$8,379	$6,445

DURECT CORPORATION
CONDENSED BALANCE SHEET
(in thousands)

	As of September 30, 2009 (unaudited)	As of December 31, 2008 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$17,933	$29,445
Short-term investments	27,483	20,836
Short-term restricted investments	372	624
Accounts receivable	2,947	4,055
Inventories	2,882	3,474
Prepaid expenses and other current assets	1,020	1,850
Total current assets	52,637	60,284
Property and equipment, net	4,516	5,971
Goodwill	6,399	6,399
Intangible assets, net	121	157
Long-term investments	1,000	1,362
Long-term restricted Investments	431	425
Other long-term assets	360	276
Total assets	$65,464	$74,874
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$498	$1,018
Accrued liabilities	5,271	5,204
Contract research liability	797	995
Deferred revenue, current portion	5,073	9,235
Other short-term liabilities	435	431
Total current liabilities	12,074	16,883
Deferred revenue, noncurrent portion	18,366	19,771
Other long-term liabilities	561	656
Stockholders' equity	34,463	37,564
Total liabilities and stockholders' equity	$65,464	$74,874

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

http://www.www.durect.com