DURECT Corporation Announces Second Quarter 2009 Financial

Results

CUPERTINO, Calif., Aug 03, 2009 /PRNewswire-FirstCall via COMTEX/ —
DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2009. Total revenues were $4.9 million for the three months ended June 30, 2009, compared to $6.3 million for the same period in 2008. Net loss for the three months ended June 30, 2009 was $7.5 million, compared to a net loss of $8.6 million for the same period in 2008.

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

At June 30, 2009, DURECT had cash and investments of $41.9 million, compared to cash and investments of $52.7 million at December 31, 2008; these figures include restricted investments of $0.8 million at June 30, 2009 and $1.0 million at December 31, 2008.

“Our senior management team was strengthened during the second quarter through the hiring of Joe Stauffer as our Chief Medical Officer, a former anesthesiologist and FDA reviewer with directly relevant experience covering all aspects of developing pain medications,” stated James E. Brown, D.V.M., President and CEO of DURECT. “It is also noteworthy that we signed four new feasibility projects in the quarter with pharmaceutical companies to apply our SABER(TM) depot and DURIN(TM) injectable technologies to address specific drug delivery challenges for both small molecule and biologic agents. Shortly after the end of the quarter, we were pleased to learn that King Pharmaceuticals met with the FDA regarding Remoxy(R) and believes that they have a clear path forward that could allow them to resubmit the Remoxy NDA in mid-2010.”

Recent Highlights:

— Remoxy. Pain Therapeutics, our licensee, received a Complete Response Letter from the FDA in December 2008 indicating that the NDA is not approved in its present form. King Pharmaceuticals, the commercialization partner of Pain Therapeutics for Remoxy, assumed responsibility for further development of Remoxy from Pain Therapeutics in March 2009 and met with the Food and Drug Administration (FDA) on July 2, 2009 to discuss the Complete Response Letter. According to King Pharmaceuticals and Pain Therapeutics, the outcome of that meeting provided King with a clear path forward to resubmit the REMOXY NDA and to address all FDA comments in the Complete Response Letter. According to the King Pharmaceuticals / Pain Therapeutics press release, King now anticipates the resubmission of the NDA 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.

REMOXY, an investigational drug, is a 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(TM) (SABER(TM)-Bupivacaine). During the quarter, DURECT continued enrollment in our approximately 60 patient Phase IIb clinical study in shoulder surgery. In addition, Nycomed continued enrollment in a

Phase IIb study in hysterectomy patients and a Phase IIb study in shoulder surgery patients. We are in active discussions with multiple potential partners regarding licensing of the U.S./Canada and Asian rights to this program.

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. 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. During the second quarter, we continued to interact with the King team on details associated with next steps in the clinical program, which King expects to initiate this year.

ELADUR is our proprietary transdermal patch intended to provide bupivacaine 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 approval. 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.

— Feasibility Projects. During the second quarter, we signed four new feasibility projects with pharmaceutical and biotechnology companies whereby we will apply our SABER and DURIN technologies to both small molecule and biologic agents of interest to our collaborator. We undertake these 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. These feasibility projects entail anticipated revenue to DURECT of approximately $1.4 million in total during 2009.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2009 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 3 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 and TRANSDUR-Sufentanil 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 timing and content of any potential update to be provided by King Pharmaceuticals, as well as the potential royalty and other payments that may be received by DURECT from REMOXY, our possible licensing of development and commercialization rights to POSIDUR and TRANSDUR-Sufentanil to third parties, and potential agreements with third parties about licensing and development 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 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 May 7, 2009 under the heading "Risk Factors."

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

	Three months ended June 30,		Year ended June 30,	
	2009	2008	2009	2008
Collaborative research and development revenue	$2,606	$3,867	$6,351	$8,136
Product revenue, net	2,271	2,436	4,686	4,605
Total revenues	4,877	6,303	11,037	12,741
Operating expenses:				
Cost of revenues (1)	837	982	1,661	1,804
Research and development (1)	7,866	9,898	17,769	19,532
Selling, general and administrative (1)	3,777	4,086	8,034	7,976
Total operating				

expenses	12,480	14,966	27,464	29,312
Loss from operations	(7,603)	(8,663)	(16,427)	(16,571)
Other income (expense):				
Interest and other income	106	368	285	936
Interest expense	(11)	(304)	(22)	(759)
Net other income	95	64	263	177
Net loss	$(7,508)	$(8,599)	$(16,164)	$(16,394)
Net loss per share, basic and diluted	$(0.09)	$(0.11)	$(0.20)	$(0.22)
Shares used in computing basic and diluted net loss per share	82,138	75,430	82,081	74,772

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

Cost of revenues	$117	$31	$195	$66
Research and development	1,327	1,360	3,608	2,967
Selling, general and administrative	864	674	2,035	1,449
Total stock-based compensation	$2,308	$2,065	$5,838	$4,482

DURECT CORPORATION
Condensed Balance Sheet
(in thousands)

	As of June 30, 2009 (unaudited)	As of December 31, 2008 (1)
ASSETS		
Current assets:		

Cash and cash equivalents	$10,024	$29,445
Short-term investments	24,507	20,836
Short-term restricted investments	372	624
Accounts receivable	2,336	4,055
Inventories	2,737	3,474
Prepaid expenses and other current assets	3,037	1,850
Total current assets	43,013	60,284
Property and equipment, net	4,955	5,971
Goodwill	6,399	6,399
Intangible assets, net	133	157
Long-term investments	6,528	1,362
Long-term restricted Investments	428	425
Other long-term assets	368	276
Total assets	$61,824	$74,874
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$846	$1,018
Accrued liabilities	4,135	5,204
Contract research liability	616	995
Deferred revenue, current portion	8,074	9,235
Other short-term liabilities	421	431
Total current liabilities	14,092	16,883
Deferred revenue, noncurrent portion	19,552	19,771
Other long-term liabilities	614	656
Stockholders' equity	27,566	37,564
Total liabilities and stockholders' equity	$61,824	$74,874

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

http://www.www.durect.com