DURECT Corporation Announces Fourth Quarter and Year End 2006 Financial Results

CUPERTINO, Calif., Feb. 8 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2006. Total revenues were $5.4 million for the three months ended December 31, 2006, compared to $5.8 million for the same period in 2005. Net loss for the three months ended December 31, 2006 was $9.6 million, compared to a net loss of $6.0 million for the same period in 2005. As a result of the upfront license fee of $14 million received from our collaboration with Nycomed related to POSIDUR(TM), cash provided by operating activities was $7.0 million for the three months ended December 31, 2006, compared to $5.6 million of cash used in operating activities for the same period in 2005.

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

For the fiscal year ended December 31, 2006, total revenues were $21.9 million, compared to $28.6 million for the same period in 2005. Net loss for the year ended December 31, 2006 was $33.2 million, compared to a net loss of $18.1 million for the same period in 2005. Cash used in operating activities was $9.5 million for the year ended December 31, 2006, compared to $7.2 million of cash used in operating activities for the same period in 2005.

At December 31, 2006, DURECT had cash and investments of $81.6 million, including $1.3 million in restricted investments, compared with cash and investments of $74.3 million at September 30, 2006 and $91.0 million at December 31, 2005.

“DURECT closed the year on a strong note and with considerable momentum,” stated James E. Brown, D.V.M., President and CEO of DURECT. “DURECT currently has 5 investigational drugs in Phase II or III, and an additional investigational drug in Phase I. In the last three months, we signed a landmark collaboration with Nycomed around POSIDUR, unveiled a new wholly-owned Phase II program (TRANSDUR(TM)-Bupivacaine), and reported positive Phase I results for our second ORADUR-opioid in development.”

Highlights for DURECT in Fiscal Year 2006 include:

- POSIDUR Post-Operative Pain Relief Depot. Our POSIDUR program advanced on both a development and business front during 2006.
    - Development Progress. During 2006, our US IND was accepted, and we commenced multiple Phase II clinical trials in the U.S. and in other countries in a variety of soft-tissue and orthopedic surgeries for the purpose of selecting the optimal dosing and the surgical procedures for our pivotal Phase III trials.
    - Business Progress. In November 2006, we signed a $202 million collaboration agreement with Nycomed, one of the top 25 pharmaceutical companies in the world. Under the terms of the agreement, DURECT has licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union

(E.U.) and select other countries. Nycomed has paid DURECT an upfront license fee of $14 million, with future potential additional milestone payments of up to $188 million upon achievement of defined development, regulatory and sales milestones. The two parties will jointly direct and equally fund a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. In addition, DURECT will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay DURECT blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. Nycomed has a strong surgical suite salesforce, along with excellent clinical and regulatory capabilities. DURECT has retained full commercial rights to POSIDUR in the U.S., Canada, Asia and other countries.

- Remoxy(TM). Remoxy, an abuse-resistant long-acting form of oxycodone based on our ORADUR(TM) technology, completed a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) and then commenced a pivotal Phase III trial in the first half of 2006 in accordance with that SPA. Remoxy is licensed to Pain Therapeutics, which has in turn sublicensed commercialization rights to King Pharmaceuticals.
- TRANSDUR-Sufentanil. During 2006, our main activity under this program involved supply of product for on-going clinical and non-clinical studies conducted by Endo Pharmaceuticals. In addition, we were engaged in technology transfer to the commercial transdermal patch manufacturer (3M Company) contracted by Endo to produce additional Phase II supplies, Phase III supplies and then commercial supplies.
- TRANSDUR-Bupivacaine. We announced that we had successfully completed Phase I clinical trials in December 2006 and announced the initiation of Phase II clinical studies in January 2007 for our TRANSDUR-Bupivacaine (DUR-843) drug candidate, a patch based on our proprietary TRANSDUR transdermal technology that is intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches. DURECT's Phase II program for TRANSDUR-Bupivacaine has begun in the U.S. under an FDA-accepted Investigational New Drug (IND) application with a randomized, multi-center, double-blind, placebo controlled, two-way crossover trial in approximately 50 patients with Post-Herpetic Neuralgia (PHN or post-shingles pain). DURECT retains full commercial rights to this drug candidate.
- Other ORADUR Products. During 2006, we worked with King and Pain Therapeutics on the development of a second ORADUR abuse-resistant opioid product. In August 2006, King and Pain Therapeutics announced the initiation of a Phase I clinical trial for a new ORADUR-based opioid investigational drug, and that the FDA had accepted the IND for this investigational drug. In November 2006, Pain Therapeutics announced positive results from that Phase I clinical trial.

Financial Guidance for 2007 and Major Potential Milestones Over the Next 12-18 Months

- Financial Guidance. Our cash burn rate is heavily influenced by the timing and structure of new corporate collaborations. While we anticipate entering into new collaborations in 2007 and beyond, assuming no new collaborations and aggressive funding of our R&D programs, many of which are in clinical development, we anticipate cash burn in 2007 of approximately $32-36 million.
- Business Development Activities. We have multiple programs that may potentially be partnered over the next 12-18 months. These include TRANSDUR-Bupivacaine, TRANSDUR-Sufentanil for Europe and for Asia, POSIDUR for Asia, as well as various internal programs which we have not described publicly in detail.
- POSIDUR(TM) Post-Operative Pain Relief Depot. During the course of 2007, we expect to provide data from our on-going Phase II trials. Pending the successful completion of our on-going Phase II trials and approval of regulatory authorities, we anticipate commencing our Phase III program in 2007.
- Remoxy. Our partner, Pain Therapeutics, has stated that they believe that they remain on track to announce results of a Phase III trial with Remoxy in the first half of 2007, followed by an NDA filing for Remoxy three quarters after data release.
- TRANSDUR-Sufentanil Patch. Based on public disclosures, Endo Pharmaceuticals has stated that it expects to conduct additional Phase II studies with the TRANSDUR-Sufentanil patch in the first half of 2007 with patches supplied from its contract manufacturer (3M Company).
- TRANSDUR-Bupivacaine Patch. During the course of 2007, we anticipate announcing the results of our current Phase II clinical trial.
- Memryte(TM) Program. Our collaborator, Voyager Pharmaceutical, has informed DURECT that Voyager has truncated its Phase III clinical trial for Memryte for the treatment of Alzheimer's Disease in order to get an early look at potential efficacy. Voyager anticipates that data from this truncated trial will be available in the first half of 2007.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies. The company is developing pharmaceutical systems to deliver the right drug to the right place in the right amount at the right time to treat chronic and episodic diseases and conditions. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding DURECT's products in development, product development plans, anticipated regulatory, clinical and development milestones and timing thereof, future clinical trial results, anticipated future collaborative agreements, projected financial results and DURECT's emergence as a specialty pharmaceutical company 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, DURECT's (and that of its third party collaborators where applicable) abilities to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies, enter into additional collaborative agreements and manufacture and commercialize the product candidate, as well as marketplace acceptance of the product candidate, 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 3, 2006 under the heading "Risk Factors."

DURECT CORPORATION

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

	Three months ended December 31,		Year ended December 31,	
	2006	2005	2006	2005
Collaborative research and development and other revenue	$3,522	$4,136	$13,786	$20,032
Product revenue, net	1,919	1,640	8,108	6,939
Revenue from sale of intellectual property rights	-	-	-	1,600
Total revenues	5,441	5,776	21,894	28,571
Operating expenses:				
Cost of revenues (1)	981	882	3,246	2,815
Research and development (1)	11,497	7,840	37,140	29,141
Selling, general and administrative (1)	2,829	2,672	12,369	11,034
Amortization of intangible assets	8	300	424	1,209
Total operating expenses	15,315	11,694	53,179	44,199
Loss from operations	(9,874)	(5,918)	(31,285)	(15,628)
Other income (expense):				
Interest and other income	991	911	3,832	2,270
Interest expense	(717)	(1,034)	(3,436)	(4,363)
Debt conversion expense	-	-	(2,287)	(403)
Net other income (expense)	274	(123)	(1,891)	(2,496)
Loss before income taxes	(9,600)	(6,041)	(33,176)	(18,124)
Income tax provision	-	-	-	4
Net loss	$(9,600)	$(6,041)	$(33,176)	$(18,128)

Net loss per common share, basic and diluted	$(0.14)	$(0.10)	$(0.50)	$(0.34)
Shares used in computing basic and diluted net loss per share	68,980	58,201	65,961	53,719
(1) Stock-based compensation related to the following:				
Cost of revenues	$26	$-	$72	$-
Research and development	699	131	2,784	237
Selling, general and administrative	372	7	1,384	354
	$1,097	$138	$4,240	$591

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	December 31, 2006 (unaudited)	December 31, 2005 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$41,554	$65,542
Short-term investments	28,297	18,022
Restricted investments	-	321
Accounts receivable, net	2,152	4,488
Inventories	2,052	2,047
Prepaid expenses and other current assets	1,744	3,659
Total current assets	75,799	94,079
Property and equipment, net	7,451	7,304
Goodwill	6,399	6,399
Intangible assets, net	111	536
Long-term investments	10,472	5,459
Restricted investments	1,284	1,653
Other long-term assets	969	1,984
Total assets	$102,485	$117,414
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$864	$1,835
Accrued liabilities	4,522	3,874
Contract research liabilities	1,624	1,418
Interest payable on convertible notes	97	149
Deferred revenue, current portion	5,348	2,367
Equipment financing obligations and term loan, current portion	34	34

Bonds payable, current portion	210	200
Total current liabilities	12,699	9,877
Bonds payable, equipment financing obligations and term loan, noncurrent portion	606	702
Convertible subordinated notes	37,337	57,337
Deferred revenue, noncurrent portion	14,507	6,016
Other long-term liabilities	304	130
Stockholders' equity	37,032	43,352
Total liabilities and stockholders' equity	$102,485	$117,414

(1) Derived from audited financial statements.

SOURCE DURECT Corporation
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