Aradigm Announces Fourth Quarter 2011 and Full Year Financial Results

HAYWARD, Calif.--(BUSINESS WIRE)-- **Aradigm Corporation (OTCBB:ARDM)** (the "Company") today announced financial results for the fourth quarter and full year ended December 31, 2011.

The Company recorded $183,000 in revenue in the fourth quarter of 2011 compared with $144,000 in revenue in the fourth quarter of 2010. Total operating expenses for the fourth quarter of 2011 were $1.3 million, compared with total operating expenses of $3.2 million for the fourth quarter of 2010. The decrease in operating expenses was due to lower research and development expenses reflecting the completion of the Phase 2b clinical trials for the inhaled ciprofloxacin program. The Company's net loss for the fourth quarter of 2011 was $1.5 million, or $0.01 per share, compared with a net loss of $2.4 million, or $0.01 per share, for the same period in 2010.

Full Year Results

Revenues for the year ended December 31, 2011 were $0.8 million, compared with revenues of $4.4 million in 2010. The decrease in revenue was due to the fact that revenues in 2010 included the non-recurring $4 million milestone payment from Zogenix, Inc. upon the initial commercialization of the SUMAVEL® DosePro™ (sumatriptan injection) needle-free delivery system.

Total operating expenses for 2011 were $9.3 million, compared with total operating expenses of $14.7 million in 2010. Research and development expenses decreased by $5.2 million and general and administrative expenses decreased by $0.2 million. The decrease in research and development expenses reflects the completion of the ORBIT-1 and ORBIT-2 bronchiectasis clinical trials of the Company's inhaled ciprofloxacin product candidates, Pulmaquin™ and Lipoquin™. The decrease in general and administrative expenses was primarily due to lower stock compensation expense.

The net loss for the year ended December 31, 2011 was $9.3 million, or $0.05 per share, compared with a net loss of $5.4 million, or $0.04 per share, in 2010. The net loss for the year ended December 31, 2010 included the $4.4 million non-cash gain on the extinguishment of debt from the equity for debt transaction with Novo Nordisk A/S.

As of December 31, 2011, cash, cash equivalents and short-term investments totaled $8.7 million.

2011 and Recent Highlights

- **March 2012: received clearance from the FDA for BE IND.** On March 12, 2012, the Company announced that its Investigational New Drug Application (IND) to conduct a pivotal Phase 3 clinical trial of Pulmaquin (dual release ciprofloxacin for inhalation) in non-cystic fibrosis bronchiectasis (BE) was cleared by the U.S. Food and Drug Administration (FDA).
- **February 2012 and December 2011: patents issued for Pulmaquin.** On February 21, 2012, the Company announced that the United States Patent and Trademark Office (USPTO) issued an important composition of matter patent covering formulations of liposomal and free ciprofloxacin, including its lead product candidate, Pulmaquin. The Company expects that the patent will provide exclusivity for Pulmaquin until October 22, 2028. On December 7, 2011, the Company announced that the USPTO issued a method of treatment patent for Pulmaquin.
- **July 2011: closed the private placement raising $4.75 million in aggregate proceeds**. On July 6, 2011, the Company announced that it entered into a definitive agreement for the sale of common stock to three existing shareholders, including accounts managed by First Eagle Investment Management LLC and Tavistock Life Sciences, in a private placement for aggregate gross proceeds of $4.75 million. Under the terms of the agreement, the Company agreed to sell an aggregate of 25,000,000 shares of common stock at a price of $0.19 per share. After deducting for fees and expenses, the net proceeds from the sale of the shares of common stock were approximately $4.4 million.
- **June 2011: closed the royalty financing transaction raising $8.5 million in aggregate proceeds.** On June 22, 2011, the Company announced that it entered into an $8.5 million royalty financing agreement with a syndicate of lenders arranged by PBS Capital Management LLC. The agreement created a debt obligation that will be repaid through and secured by royalties from net sales of the SUMAVEL® DosePro™ (sumatriptan injection) needle-free delivery system payable to Aradigm under its Asset Purchase Agreement ("APA") with Zogenix, Inc. The APA provides for Aradigm to receive a 3% royalty on net sales of SUMAVEL DosePro in all territories. Under the terms of the royalty financing agreement, the Company received a loan of $8.5 million, less fees and expenses (approximately $473,000)

and an additional $250,000 set aside for an Interest Reserve Account. The lenders are entitled to receive 100% of all royalties payable to Aradigm under the APA until the principal and accrued interest of the Term Loan are fully repaid, after which time the benefit of any further royalties made under the APA will accrue to Aradigm.

- **June 2011: announced positive top line data from the ORBIT-1 study**. On June 16, 2011, the Company announced positive top line data from its multi-center Phase 2b study (Once-Daily Respiratory Bronchiectasis Inhalation Treatment - ORBIT-1) with Lipoquin (ciprofloxacin for inhalation, ARD-3100) in patients with BE. The primary endpoint - the mean change in *Pseudomonas aeruginosa* colony forming units per gram of sputum (CFUs) from baseline to day 28 — was met in the full analysis population.
- **June 2011: announced receipt of FDA orphan drug status for ciprofloxacin for inhalation for BE.** On June 6, 2011, the Company announced it received orphan drug designation from the FDA for ciprofloxacin for inhalation for the management of BE. Previously, the Company received orphan drug designations from the FDA for liposomal ciprofloxacin for inhalation for the management of BE and for liposomal ciprofloxacin for the management of cystic fibrosis. Orphan drug designation is intended to encourage research and development of new therapies for diseases that affect fewer than 200,000 patients in the United States. As a designated orphan drug, the Company's ciprofloxacin drug candidates are eligible for tax credits based upon their clinical development costs, as well as assistance from the FDA in guiding the drug candidates through the regulatory approval process. The designation also provides the opportunity to obtain market exclusivity for seven years from the date of NDA approval even in the absence of patent protection.

"In the last year, we completed several important transactions, including the royalty financing transaction and the July 2011 private placement, that strengthened our balance sheet and allowed us to advance our lead product candidate, Pulmaquin, to Phase 3 readiness with the clearance of the U.S. IND in March 2012," said Nancy E. Pecota, the Company's Vice President and CFO. "We continue our focus on prudent cash management as we prepare to enter Phase 3 clinical trials for Pulmaquin in non-cystic fibrosis bronchiectasis with a partner with the goal of bringing a much needed treatment to this under-served orphan patient population."

About Aradigm

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of drugs delivered by inhalation for the prevention and treatment of severe respiratory diseases by pulmonologists. The Company has product candidates addressing the treatment of bronchiectasis, cystic fibrosis, inhalation tularemia and anthrax infections, and prevention of respiratory and other diseases in tobacco smokers through smoking cessation.

More information about Aradigm can be found at www.aradigm.com.

About Pulmaquin

Pulmaquin (ARD-3150) is a once-a-day novel inhaled formulation consisting of a proprietary mixture of unencapsulated ciprofloxacin and ciprofloxacin encapsulated in liposomes (Lipoquin), allowing for both immediate and sustained release of the drug within the lung. Ciprofloxacin is a widely prescribed antibiotic to treat infections of the lung frequently experienced by non-cystic fibrosis bronchiectasis (BE) patients. It is often preferred because of its broad-spectrum anti-bacterial action. The available oral and intravenous formulations of the drug are used to treat episodes of acute exacerbations of lung infections in BE patients. Pulmaquin is to be used for chronic maintenance therapy as it is expected to achieve higher antibiotic concentration at the site of infection and relatively low systemic antibiotic concentrations to minimize side-effects. The ORBIT-2 Phase 2b study with Pulmaquin demonstrated positive results with outstanding antimicrobial activity and a significant impact on the prevention of pulmonary exacerbations. The Phase 3 clinical program for BE will consist of two identical placebo controlled trials enrolling approximately 250 patients per trial with one year duration and a design similar to the ORBIT-2 trial. Aradigm has been granted orphan drug designation for inhaled ciprofloxacin for BE in the U.S.

Forward-Looking Statements

Except for the historical information contained herein, this news release contains forward-looking statements that involve risk and uncertainties, including the timing and results of clinical trials and continued receipt of royalties from Zogenix, Inc., as well as the other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC on March 25, 2011, and the Company's Quarterly Reports on Form 10-Q.

ARADIGM CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2011	2010	2011	2010
Revenue	$ 183	$ 144	$ 791	$ 4,383
Operating expenses:				
Research and development	651	2,234	5,007	10,210
General and administrative	679	955	4,274	4,485
Restructuring and asset impairment	9	11	39	48
Total operating expenses	1,339	3,200	9,320	14,743
Loss from operations	(1,156)	(3,056)	(8,529)	(10,360)
Interest income	5	3	14	20
Interest expense	(370)	(5)	(798)	(318)
Other income (expense), net	2	723	4	844
Gain (loss) from extinguishment of debt	-	(27)	-	4,435
Net loss	$ (1,519)	$ (2,362)	$ (9,309)	$ (5,379)
Basic and diluted net loss per common share	$ (0.01)	$ (0.01)	$ (0.05)	$ (0.04)
Shares used in computing basic and diluted net loss per common share	197,833	169,824	183,419	128,660

ARADIGM CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,148	$ 5,295
Short-term investments	6,516	251
Receivables	36	180
Prepaid and other current assets	161	180
Total current assets	8,861	5,906
Property and equipment, net	1,113	1,553
Notes receivable	29	54
Other assets	553	115
Total assets	$ 10,556	$ 7,628
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	196	257
Accrued clinical and cost of other studies	247	993
Accrued compensation	195	327
Facility lease exit obligation	120	99
Other accrued liabilities	86	450
Total current liabilities	844	2,126
Deferred rent, non-current	132	99
Facility lease exit obligation, non-current	609	729
Other non-current liabilities	75	75

Note payable and accrued interest	8,207	-
Shareholders' equity	689	4,599
Total liabilities and shareholders' equity	$ 10,556	$ 7,628

Aradigm Corporation
Nancy Pecota, Chief Financial Officer, 510-265-8800

Source: Aradigm Corporation