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Aradigm Announces Fourth Quarter 2015 and Full Year Financial Results

HAYWARD, Calif.--(BUSINESS WIRE)-- **Aradigm Corporation (NASDAQ:ARDM)** (the "Company") today announced financial results for the fourth quarter and full year ended December 31, 2015.

Fourth Quarter 2015 Results

Since the Company has utilized the full amount of the $65 million of Grifols-funded budget provided under the inhaled ciprofloxacin collaboration arrangement which is recognized as revenue for reimbursement of its investigational drug Pulmaquin® inhaled ciprofloxacin project-related costs the Company recorded $35,000 in revenue in the fourth quarter of 2015 compared with $8.1 million in revenue in the fourth quarter of 2014. The Company will not be recognizing any future revenue related to the $65 million Grifols-funded budget. Total operating expenses for the fourth quarter of 2015 were $9.4 million, compared with total operating expenses of $8.9 million for the fourth quarter of 2014. The increase in operating expenses was primarily due to higher research and development expenses related to the ongoing Pulmaquin Phase 3 clinical trials. The Company's net loss for the fourth quarter of 2015 was $9.4 million, or $0.63 per share, compared with a net loss of $0.8 million, or $0.06 per share, for the same period in 2014.

Full Year Results

Revenues for the year ended December 31, 2015 were $23.4 million, compared with revenues of $33.6 million in 2014. The decrease in revenue was due to full utilization in 2015 of the $65 million of Grifols-funded budget for Pulmaquin project-related costs which are recognized as revenue under the Grifols collaboration arrangement.

Total operating expenses for 2015 were $40.6 million, compared with total operating expenses of $37.4 million in 2014. Research and development expenses increased by $4.1 million and general and administrative expenses decreased by $0.9 million. The increase in research and development expenses was due to higher contract manufacturing, contract testing and clinical trial costs related to the Pulmaquin program, higher employee-related expenses due to the addition of staff, offset by a decrease in consulting expenses in support of the Pulmaquin program. The decrease in general and administrative costs was due to lower consulting expenses, lower officer bonuses, lower legal expenses and lower expenses for NASDAQ and public filings offset by an increase in employee-related costs for the addition of staff.

The net loss for the year ended December 31, 2015 was $17.2 million, or $1.17 per share, compared with net income of $4.7 million, or $0.32 per share, in 2014. Net loss increased in 2015 over 2014 due to lower collaboration revenue of $9.7 million, an increase in Pulmaquin-related project expenses of $4.1 million and the one-time, non-cash gain of $8.9 million from the assignment of royalty rights and extinguishment of debt that occurred in 2014, offset by a decrease of general and administrative expenses of $0.9 million.

As of December 31, 2015, cash and cash equivalents totaled $31.5 million.

"The completion of the enrollment of our pivotal Phase 3 clinical program for bronchiectasis last year was a critical achievement for Aradigm. All our efforts are now focused on having the key data analyses for both trials completed this year to enable us to file the US NDA early in 2017, followed by submission for market authorization in the European Union," said Igor Gonda, CEO and President of Aradigm.

2015 Highlights

- **October 2015 - The Company announced the completion of enrollment in the ORBIT-3 trial**, the second of the two fully enrolled Phase 3 pivotal clinical trials of Pulmaquin for the treatment of patients with non-cystic fibrosis bronchiectasis who have chronic lung infections with *Pseudomonas aeruginosa*. ORBIT-3 is a worldwide, double-blind, placebo-controlled pivotal trial that enrolled 278 patients across 17 countries, including the U.S., Canada, Australia, New Zealand, Israel, South Korea, Taiwan, South Africa and countries in Europe.
- **September 2015 - The Company announced the completion of enrollment in the ORBIT-4 Phase 3 pivotal clinical trial of Pulmaquin**, Aradigm's proprietary investigational formulation of inhaled ciprofloxacin, for the treatment of patients with non-cystic fibrosis bronchiectasis who have chronic lung infections with *Pseudomonas aeruginosa*. ORBIT-4 is one of two Phase 3 pivotal clinical trials Aradigm is conducting with Pulmaquin in this patient

population with an unmet medical need. The worldwide, double-blind, placebo-controlled pivotal trial enrolled 304 patients across 16 countries, including the U.S., Canada, Australia, New Zealand, Israel, South Korea, Peru and countries in Europe.

- **July 2015 - The United States Patent and Trademark Office issued a composition of matter patent (U.S. Patent No. 9,078,897)** covering formulations of liposomal and free ciprofloxacin, including Aradigm's lead product candidate, Pulmaquin. This represents the sixth issued U.S. patent covering Aradigm's liposomal ciprofloxacin formulations.
- **May 2015 - The Company announced that scientists from the Oregon State University, Corvallis and Aradigm demonstrated that Aradigm's investigational drugs Lipoquin and Pulmaquin significantly reduced the growth of pulmonary non-tuberculous mycobacteria (PNTM) after 3 weeks of once daily respiratory tract dosing in a mouse model.** The number of colony forming units of Mycobacterium *Avium Subsp Hominissuis* was reduced by 79% and 77% by Lipoquin and Pulmaquin, respectively ($p < 0.05$) compared to saline controls. In contrast, unencapsulated ciprofloxacin had no effect. The detailed description of this research and its findings was presented at the American Thoracic Society 2015 International Conference in Denver, CO.

About Pulmaquin

Pulmaquin is a dual release formulation composed of a mixture of liposome encapsulated and unencapsulated ciprofloxacin. Ciprofloxacin, available in oral and intravenous formulations, is a widely prescribed antibiotic. It is used to treat acute lung infections and is often preferred because of its broad-spectrum antibacterial activity against various bacteria, such as *Pseudomonas aeruginosa*. Pulmaquin is being evaluated in two ongoing Phase 3 studies to determine its safety and effectiveness as a once-a-day inhaled formulation for the chronic treatment of patients with non-CF BE who have chronic lung infections with *Pseudomonas aeruginosa*.

Following Phase 2a development of the liposomal portion of Pulmaquin (Lipoquin®) and Phase 1 development of Pulmaquin, the Phase 2b study ORBIT-2 with Pulmaquin was a 24-week multicenter, randomized, double-blind, placebo-controlled trial in 42 adult non-CF BE subjects. This study demonstrated a significant reduction in *P.aeruginosa* sputum activity ($p=0.002$) and a decrease in time to first exacerbation in the per protocol population ($p=0.046$) and the mITT ($p=0.057$) populations in the Pulmaquin treated subjects compared to placebo. Overall, the incidence of all treatment emergent adverse events was similar between groups. The most frequently reported treatment related adverse events (reported by ≥ 3 patients in either treatment group) included product taste abnormal and nausea in the Pulmaquin group and wheezing in the placebo group. No serious adverse events were considered treatment related. There were no deaths reported during ORBIT-2.

The Phase 3 clinical program for Pulmaquin in non-CF BE consists of two worldwide, double-blind, placebo-controlled pivotal trials (ORBIT-3 and ORBIT-4) that are identical in design except for a pharmacokinetics sub-study to be conducted in one of the trials. Each trial has enrolled patients (278 in ORBIT-3 and 304 in ORBIT-4) into a 48-week double-blind period consisting of 6 cycles of 28 days on treatment with Pulmaquin or placebo plus 28 days off treatment, followed by a 28 day open label extension in which all participants will receive Pulmaquin (total treatment duration approximately one year). The superiority of Pulmaquin vs. placebo during the double-blind period is being evaluated in terms of the time to first pulmonary exacerbation (primary endpoint), while key secondary endpoints include the reduction in the number of pulmonary exacerbations and improvements in the quality of life measures. Lung function is being monitored as a safety indicator.

Aradigm has been granted orphan drug designations for liposomal ciprofloxacin as well as for ciprofloxacin for inhalation for non-CF BE in the U.S. In addition, the U.S. Food and Drug Administration (FDA) has designated Pulmaquin as a Qualified Infectious Disease Product (QIDP). The QIDP designation is granted for treatment of non-CF BE patients with chronic lung infections with *Pseudomonas aeruginosa*. The QIDP designation made Pulmaquin eligible for Fast Track designation which was granted by the FDA in September 2014.

In 2013, Aradigm granted an exclusive, world-wide license for the Company's inhaled liposomal ciprofloxacin product candidates for the indication of non-CF BE and other indications to Grifols S.A. More information on the terms of this license may be found in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 13, 2014.

About Non-Cystic Fibrosis Bronchiectasis

Non-CF BE is a severe, chronic and rare disease characterized by abnormal dilatation of the bronchi and bronchioles, frequently associated with chronic lung infections. It is often a consequence of a vicious cycle of inflammation, recurrent lung infections, and bronchial wall damage. Non-CF BE represents an unmet medical need with high morbidity and mortality that affects more than 110,000 people in the U.S. and over 200,000 people in Europe. There is currently no drug approved for the treatment of this condition.

About Aradigm

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of drugs for the prevention and treatment of severe respiratory diseases. Aradigm is currently in Phase 3 development of Pulmaquin (an investigational proprietary formulation of ciprofloxacin for inhalation) for the treatment of non-cystic fibrosis bronchiectasis. Aradigm's inhaled ciprofloxacin formulations are also product candidates for treatment of patients with cystic fibrosis and non-tuberculous mycobacteria, and for the prevention and treatment of high threat and bioterrorism infections, such as inhaled tularemia, pneumonic plague, melioidosis, Q fever and inhaled anthrax. In addition, Aradigm has a pipeline composed of programs to prevent diseases in tobacco smokers through smoking cessation and a diagnostic program to detect aspirations of gastrointestinal fluid into the respiratory tract.

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

Forward-Looking Statements

Except for the historical information contained herein, this news release contains forward-looking statements that involve risk and uncertainties, including those related to the ORBIT-3 and ORBIT-4 clinical trials and the ability to continue successful product development of our potential product candidates, including Pulmaquin, 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, 2014 filed with the SEC on March 18, 2015, 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,	
	2015	2014	2015	2014
Revenue:				
Contract revenue - related party	$ -	$ 8,050	$ 23,372	$33,038
Grant revenue	35	18	57	323
Royalty revenue	-	-	-	200
Total revenues	35	8,068	23,429	33,561
Operating expenses:				
Research and development	8,281	7,673	35,276	31,172
General and administrative	1,093	1,201	5,294	6,226
Restructuring and asset impairment	2	4	11	19
Total operating expenses	9,376	8,878	40,581	37,417
Loss from operations	(9,341)	(810)	(17,152)	(3,856)
Interest income	7	9	29	17
Interest expense	-	-	-	(288)
Other expense, net	(18)	(30)	(86)	(85)
Gain on assignment of royalty interests	-	-	-	5,823
Gain from extinguishment of debt	-	-	-	3,041
Net income (loss) and comprehensive income (loss)	$ (9,352)	$ (831)	$(17,209)	$ 4,652
Basic net income (loss) per common share	$ (0.63)	$ (0.06)	$ (1.17)	$ 0.32
Diluted net income (loss) per common share	$ (0.63)	$ (0.06)	$ (1.17)	$ 0.32
Shares used in computing basic net income (loss) per common share	14,761	14,726	14,747	14,700

Shares used in computing diluted net income (loss) per common share	14,761	14,726	14,747	14,726

ARADIGM CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,462	$ 47,990
Restricted cash	-	250
Receivables	150	1,058
Prepaid and other current assets	3,634	1,207
Total current assets	35,246	50,505
Property and equipment, net	299	502
Other assets	81	2,956
Total assets	$ 35,626	$ 53,963
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,789	2,706
Accrued clinical and cost of other studies	4,315	2,070
Accrued compensation	1,159	819
Deferred revenue - related party	-	790
Deferred rent	37	
Facility lease exit obligation	104	193
Other accrued liabilities	112	191
Total current liabilities	7,516	6,769
Accrued clinical and cost of other studies, non-current	-	33
Deferred rent, non-current	-	97
Facility lease exit obligation, non-current	-	104
Deferred revenue - related party, non-current	5,000	7,845
Shareholders' equity	23,110	39,115
Total liabilities and shareholders' equity	$ 35,626	$ 53,963

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