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Aradigm Announces Second Quarter 2016 Financial Results

HAYWARD, Calif.--(BUSINESS WIRE)-- **Aradigm Corporation (NASDAQ: ARDM)** (the "Company") today announced financial results for the second quarter and six months ended June 30, 2016.

Second Quarter 2016 Financial Results

The Company recorded \$14,000 in revenue in the second quarter of 2016 compared with \$10 million in revenue in the second quarter of 2015. The reduction in revenue occurred because the Company utilized in prior periods the full amount of the \$65 million of Grifols-funded budget provided under the inhaled ciprofloxacin collaboration arrangement for funding the bronchiectasis program.

Total operating expenses for the second quarter of 2016 were \$7.6 million, compared with total operating expenses of \$11.1 million for the second quarter of 2015. The decrease in research and development expenses was due to lower contract manufacturing and clinical trial costs because the manufacturing, labeling and packaging expenses for clinical supplies and the enrollment activities of the Pulmaquin Phase 3 clinical trials are complete, offset by higher employee-related expenses due to the higher number of employees and higher consulting expenses in support of the Pulmaquin bronchiectasis regulatory process towards US and EU approvals for market authorization.

Net loss for the second quarter of 2016 was \$8.7 million or \$0.59 per share, compared with a net loss of \$1.1 million or \$0.08 per share in the second quarter of 2015. Net loss increased due to lower contract revenue of \$9.9 million, partially offset by lower operating expenses of \$3.5 million.

Liquidity and Capital Resources

In April 2016, the Company entered into a private placement conducted pursuant to Regulation D under the Securities Act of 1933, as amended, of \$23 million of its senior convertible notes due 2021 and related warrants to purchase 263,436 shares of the Company's common stock. The convertible notes are initially convertible into 191,9386 shares of common stock for each \$1,000 principal amount of notes, which represents an initial conversion price of approximately \$5.21 per share of common stock. Interest on the notes will be paid semi-annually in arrears at the rate of 9% per year. The warrants are exercisable at an exercise price of \$5.21 per share beginning on the later of 180 days after the date of issuance or the date the Company issues a press release announcing data related to the ORBIT-3 and ORBIT-4 Phase 3 pivotal clinical trials in non-cystic fibrosis bronchiectasis (non-CF BE) patients with chronic respiratory infections with *Pseudomonas aeruginosa* treated with the Company's investigational product Pulmaquin® (proprietary formulation of inhaled ciprofloxacin). The first closing of the sale of the notes and warrants occurred on April 25, 2016 and the second closing occurred on July 14, 2016.

The Company intends to use the net proceeds from the offering, estimated to be \$20.7 million, to fund the current clinical development and regulatory submission for licensure of Pulmaquin and for general corporate purposes.

As of June 30, 2016, the Company reported cash and cash equivalents of \$31.2 million which did not include gross proceeds of \$3 million from the second closing of the private placement offering of \$23 million senior convertible notes.

"Our pivotal Phase 3 studies, ORBIT-3 and ORBIT-4, are on track to complete the double blind portion of each trial in the coming months and we expect topline data to be available by the end of this year. The manufacturing of Pulmaquin is now at commercial scale and is able to supply the launch quantities for our partner Grifols, who are actively working on preparations for product launch following NDA filing and FDA approval," said Igor Gonda, President and CEO of the Company. "In addition, we continue to grow the Pulmaquin-related patent estate which now stands at 7 issued patents in the U.S. and 39 issued patents in geographies outside the U.S."

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, including the double-blind period, of 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, 2015 filed with the SEC on March 30, 2016, and the

Company's Quarterly Reports on Form 10-Q.

Aradigm, Pulmaquin, Lipoquin and the Aradigm Logo are registered trademarks of Aradigm Corporation.

ARADIGM CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)
(Unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenues	\$ 14	\$ 9,952	\$ 20	\$ 18,720
Operating expenses:				
Research and development	6,235	9,754	12,686	18,115
General and administrative	1,385	1,339	3,029	2,881
Restructuring and asset impairment	1	3	2	7
	<u>7,621</u>	<u>11,096</u>	<u>15,717</u>	<u>21,003</u>
Loss from operations	(7,607)	(1,144)	(15,697)	(2,283)
Interest income	26	7	36	15
Interest expense	(577)	-	(577)	-
Other expense	(571)	(8)	(577)	(40)
	<u>\$ (8,729)</u>	<u>\$ (1,145)</u>	<u>\$ (16,815)</u>	<u>\$ (2,308)</u>
Comprehensive loss	<u>\$ (8,729)</u>	<u>\$ (1,145)</u>	<u>\$ (16,815)</u>	<u>\$ (2,308)</u>
Basic and diluted net loss per common share	<u>\$ (0.59)</u>	<u>\$ (0.08)</u>	<u>\$ (1.14)</u>	<u>\$ (0.16)</u>
Shares used in computing basic and diluted net loss per common share	14,778	14,749	14,769	14,738

ARADIGM CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2016	December 31, 2015
	(Unaudited)	*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,213	\$ 31,462
Restricted cash	1,800	-
Receivables	330	150
Prepaid and other current assets	2,332	3,634
	<u>35,675</u>	<u>35,246</u>
Property and equipment, net	282	299
Other assets	81	81
	<u>\$ 36,038</u>	<u>\$ 35,626</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,151	1,789
Accrued clinical and cost of other studies	2,346	4,315

Accrued compensation	1,021	1,159
Deferred rent	-	37
Facility lease exit obligation	4	104
Other accrued liabilities	696	112
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Total current liabilities	5,218	7,516
Deferred revenue - related party, non-current	5,000	5,000
Convertible debt - related party, net of discount	10,292	-
Total liabilities	20,510	12,516
Shareholders' equity	15,528	23,110
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Total liabilities and shareholders' equity	\$ 36,038	\$ 35,626

* The balance sheet at December 31, 2015 has been derived from the audited financial statements at that date.

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Source: Aradigm Corporation

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