August 10, 2017

Aradigm Announces Second Quarter 2017 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, 2017.

The Company recorded $7.7 million in revenue in the second quarter of 2017 compared with $14,000 in revenue in the second quarter of 2016. The Company recognized $7.5 million in contract revenue - related party, $196,000 in government contract revenue and $7,000 in government grant revenue for the second quarter of 2017, as compared to $14,000 in government grant revenue for the second quarter of 2016. The increase in revenue was from the Company's adoption of ASC Topic 606 *Revenue from Contracts with Customers* and primarily resulted from a change in estimated variable consideration associated with the $5 million regulatory milestone for the New Drug Application (NDA) submittal.

Total operating expenses for the second quarter of 2017 were $5.7 million, compared with total operating expenses of $7.6 million for the second quarter of 2016. The decrease in research and development expenses of $2.4 million was due to lower contract manufacturing and clinical trial costs because the Linhaliq™ Phase 3 clinical trials in non-cystic fibrosis bronchiectasis (NCFBE) are complete, offset by higher employee-related expenses due to the higher number of employees and higher consulting expenses in support of the Linhaliq regulatory process towards U.S. and European Union approvals for market authorization. The increase in general and administrative expenses of $0.5 million was primarily related to higher legal expenses, higher non-cash stock compensation expense and higher consulting expenses.

Net income for the second quarter of 2017 was $1.0 million or $0.07 per share, compared with a net loss of $8.7 million or $0.59 per share in the second quarter of 2016. For the quarter ended June 30, 2017, the increase in net income resulted primarily from an increase in revenue of $7.7 million and a decrease in operating expenses of $1.9 million.

As of June 30, 2017, the Company reported cash and cash equivalents of $12.0 million.

"Submission of the NDA for Linhaliq to the FDA last month is the most significant milestone in the history of Aradigm. We expect a similar submission in the European Union early next year. Marketing authorizations in these two major territories would be transforming events for us," said Igor Gonda, President and CEO of the Company.

About Linhaliq

Linhaliq, formerly known as Pulmaquin®, is 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 often to treat acute lung infections because of its broad-spectrum antibacterial activity against various bacteria, such as *Pseudomonas aeruginosa*. Aradigm's once-a-day novel inhaled formulations of ciprofloxacin are encapsulated in liposomes, allowing for a sustained release of the drug within the lung and improving airway tolerability. The formulations are to be used for chronic maintenance therapy as they are expected to achieve higher antibiotic concentration at the site of infection and relatively low systemic antibiotic concentrations to minimize side-effects. Lipoquin® is a liposomal formulation of ciprofloxacin. Linhaliq is a dual release formulation that is a mixture of Lipoquin with unencapsulated ciprofloxacin. Aradigm completed two Phase 3 clinical trials with once daily inhaled Linhaliq in patients with NCFBE with chronic lung infections with *Pseudomonas aeruginosa* and submitted a New Drug Application (NDA) to the FDA for this product candidate in July 2017. Once daily inhaled Lipoquin was tested in Phase 1 and Phase 2 clinical trials in healthy subjects, cystic fibrosis patients and non-cystic fibrosis bronchiectasis patients. Aradigm received Orphan Drug Designation for liposomal ciprofloxacin for inhalation for the management of bronchiectasis and for Linhaliq for the management of bronchiectasis. Additionally, for Linhaliq, Aradigm was granted Qualified Infectious Disease Product (QIDP) Designation for the treatment of NCFBE patients with chronic lung infections with *P. aeruginosa* followed by Fast Track Designation.

About Non-Cystic Fibrosis Bronchiectasis

NCFBE 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. NCFBE represents an unmet medical need with high morbidity and mortality that affects more than 150,000 people in the U.S. and over 200,000 people in Europe. There is currently no drug approved for the treatment of this condition. NCFBE patients who have chronic infections with *P. aeruginosa* have a 6.5-fold increase in

hospitalization, three times higher mortality, and a worse quality of life compared with those without *P. aeruginosa* infections.

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 has completed Phase 3 development of Linhaliq (an investigational proprietary formulation of ciprofloxacin for inhalation) for the treatment of NCFBE. Aradigm's inhaled ciprofloxacin formulations including Linhaliq 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.

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 ability to continue successful product development of our potential product candidates, such as Linhaliq; the fact that we will require additional capital to support the US and EU regulatory process for Linhaliq or any other product candidates, and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to us; whether the NDA for Linhaliq is accepted for filing and subsequent approval by the FDA; the risk that the FDA and foreign regulatory authorities may not agree with our interpretation of the data from our clinical trials of Linhaliq and may require us to conduct additional clinical trials, 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, 2016 filed with the SEC on March 30, 2017, and the Company's Quarterly Reports on Form 10-Q.

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Revenues	$ 7,675	$ 14	$ 9,368	$ 20
Operating expenses:				
Research and development	3,794	6,235	6,568	12,686
General and administrative	1,911	1,385	3,589	3,029
Restructuring and asset impairment	-	1	-	2
Total operating expenses	5,705	7,621	10,157	15,717
Income (loss) from operations	1,970	(7,607)	(789)	(15,697)
Interest income	22	26	50	36
Interest expense	(959)	(577)	(1,912)	(577)
Other income (expense)	2	(571)	8	(577)
Net income (loss) and comprehensive income (loss)	$ 1,035	$ (8,729)	$(2,643)	$(16,815)
Basic and diluted net income (loss) per common share	$ 0.07	$ (0.59)	$ (0.18)	$ (1.14)
Shares used in computing basic net income (loss) per common share	14,847	14,778	14,823	14,769
Shares used in computing diluted net income (loss) per common share	14,848	14,778	14,823	14,769

ARADIGM CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2017 (Unaudited)	December 31, 2016 *
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,028	$ 22,591
Restricted cash	-	1,006
Receivables	340	167
Prepaid and other current assets	621	1,037
Total current assets	12,989	24,801
Property and equipment, net	227	253
Total assets	$ 13,216	$ 25,054
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	1,058	711
Accrued clinical and cost of other studies	476	3,306
Accrued compensation	1,149	1,335
Deferred revenue - related party, current	1,891	-
Deferred revenue - other	79	-
Other accrued liabilities	497	496
Total current liabilities	5,150	5,848
Deferred revenue - related party, non-current	-	5,000
Convertible debt - non-current, net of discount	2,296	2,212
Convertible debt - related party, non-current, net of discount	11,788	11,007
Total liabilities	19,234	24,067
Shareholders' equity (deficit)	(6,018)	987
Total liabilities and shareholders' equity (deficit)	$ 13,216	$ 25,054

* The balance sheet at December 31, 2016 has been derived from the audited financial statements at that date.

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Source: Aradigm Corporation