Ardea Biosciences, Inc./DE
Form 8-K
April 05, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): March 31, 2010
Ardea Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**1-33734**	**94-3200380**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4939 Directors Place **San Diego, California**	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(858) 652-6500**

Not applicable.
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 5, 2010, the Company entered into an employment agreement (the Employment Agreement) with Steven R. Davis, pursuant to which Mr. Davis will serve as the Company s Executive Vice President and Chief Operating Officer, to be effective on April 6, 2010, Mr. Davis' start date.

Mr. Davis, age 49, is the former President and Chief Executive Officer of Neurogen Corporation, which was acquired by Ligand Pharmaceuticals in December 2009. Prior to being named CEO in February 2008, Mr. Davis served as Chief Operating Officer of Neurogen beginning in April 2005 and Vice President from September 2001 through April 2005. Mr. Davis was also a director of Neurogen. Mr. Davis joined Neurogen in 1994 as Vice President of Finance and Chief Financial Officer. From 1990 through June 1994, Mr. Davis was employed by Milbank, Tweed, Hadley & McCloy LLP as a corporate and securities attorney. Previously, Mr. Davis practiced as a Certified Public Accountant with Arthur Andersen & Co. Mr. Davis received his B.S. in Accounting from Southern Nazarene University and a J.D. from Vanderbilt University. There is no family relationship between Mr. Davis and any other director or executive officer of the Company.

Under the Employment Agreement, Mr. Davis' initial annual base salary will be $350,000 and he will be eligible to receive an annual performance bonus under the Company s executive bonus plan of up to 40% of his salary. Mr. Davis will also be eligible to receive all other benefits normally offered to full-time executive-level employees. Mr. Davis will also be reimbursed for certain reasonable costs incurred in moving to the area. Additionally, Mr. Davis will be entitled to participate in our Senior Executive Severance Benefit Plan, which provides that if we terminate Mr. Davis' employment without cause or he resigns for good reason, he will be entitled, upon execution of a designated release agreement, to a severance payment equal to twelve month s base salary.

Upon commencement of his employment and subject to approval of the Company s Board of Directors, Mr. Davis will be granted an option to purchase 150,000 shares of the Company s common stock under the Company s 2004 Stock Incentive Plan. The option will vest and become exercisable over a four-year period, with 25% of the shares subject to the option vesting on the first anniversary of his employment and the balance vesting in equal monthly increments thereafter, subject in each case to his continued service to the Company. The exercise price per share of the option will be equal to the fair market value per share of the Company s common stock established on the date of grant, subject to approval by the Board.

Also upon commencement of his employment and subject to approval of the Company s Board of Directors, Mr. Davis will be granted 25,000 shares of the Company s common stock under the Company s 2004 Stock Incentive Plan, payable by Mr. Davis s future services to the Company, which stock grant will vest over a four-year period, with 25% of the shares subject to the grant vesting on the first anniversary of his employment and the balance vesting in equal monthly increments thereafter, subject in each case to his continued service to the Company.

Under the terms of the 2004 Stock Incentive Plan, in the event of a sale or disposition of substantially all of our securities or assets, a merger with or into another corporation or a consolidation or other change of control transaction involving us, the stock awards held by Mr. Davis will vest and become immediately exercisable as to half of the otherwise unvested shares underlying those awards, and any remaining unvested shares underlying those stock awards will vest in full should either of the following events occur within three months prior or 13 months after the transaction: Mr. Davis' employment is involuntarily terminated without cause or he voluntarily resigns for good reason.

Mr. Davis has also entered into the Company s standard form of Proprietary Information and Inventions Agreement.

Item 8.01. Other Events.

On March 31, 2010, Ardea Biosciences, Inc. announced positive, preliminary, top-line results from its Phase 2b monotherapy study of RDEA594, its lead product candidate for the treatment of hyperuricemia and gout. In this 28-day, randomized, double-blind, placebo-controlled, dose-escalation study, 123 gout patients with hyperuricemia (serum urate levels greater than or equal to 8 mg/dL) received 200 mg once-daily (qd) RDEA594, 400 mg qd RDEA594, 600 mg qd RDEA594 or matching placebo. For patients receiving 400 mg qd RDEA594 and 600 mg qd RDEA594, their dose was titrated up weekly in increments of 200 mg/day. This study specifically enrolled patients who excrete less than normal amounts of uric acid at baseline (under-excretors of uric acid make up approximately

90% of all gout patients). All patients received colchicine for prophylaxis against flares. The primary endpoint of the study was a significant increase in the proportion of patients who achieved a response, defined as a reduction of serum urate to < 6 mg/dL after 4 weeks of treatment, compared to placebo.

The primary endpoint was achieved in this study. Reductions in serum urate and response rates increased in a dose-related manner and were highly clinically and statistically significant at both the 400 mg qd and 600 mg qd dose levels. At the highest dose, there was a 38% median reduction in serum urate levels after 4 weeks compared to a 1% increase on placebo ($p < 0.0001$). This translated into a response rate of 45%, compared to 0% for placebo ($p < 0.0001$).

As expected, the response to treatment was highly correlated with the starting serum urate levels of the patients, as has been seen in previously conducted studies with other urate-lowering drugs. This study enrolled patients who, on average, had a higher baseline serum urate level (median 9.8 mg/dL) than observed in our previous studies. The response rate at the highest dose in patients with baseline serum urate levels of <10 mg/dL (9.2 mg/dL on average) was 58% ($p = 0.0012$). Based on the National Health and Nutrition Examination Survey (NHANES) 2007-2008, patients with serum urate levels below 10 mg/dL make up approximately 95% of the gout patients in clinical practice.

Preliminary, Top-Line Efficacy Results of Phase 2b Monotherapy Study of RDEA594 in the Treatment of Hyperuricemia in Gout Patients

	Treatment Groups			
	RDEA594 600mg qd	RDEA594 400mg qd	RDEA594 200mg qd	Placebo
Response Rate (Primary Endpoint)	45% (n=32)	28% (n=33)	7% (n=31)	0% (n=27)
p Value versus Placebo	<0.0001	0.0056	NS	
Response Rate in Pts. with Baseline Serum Urate <10 mg/dL	58% (n=12)	42% (n=14)	11% (n=18)	0% (n=14)
p Value versus Placebo	0.0012	0.016	NS	

NS = not significant

RDEA594 was well tolerated in this study. There were no serious adverse events and no difference in the rate of adverse events considered at least possibly related to treatment between the groups receiving RDEA594 and placebo. Two patients (2%) randomized to RDEA594 discontinued treatment due to an adverse event. One patient discontinued due to vertigo, while the other patient was discontinued due to a transient increase in serum creatinine that returned to normal levels prior to discontinuing drug. Because RDEA594 s target for activity (URAT1) is a transporter protein located in the kidney, careful monitoring of markers of renal function was performed, including at least weekly measurements of serum creatinine. A small number of transient increases in serum creatinine were observed both during the screening period, *prior to the administration of drug* , and during the randomized portion of the study. Specifically, 2% of serum creatinine measurements showed such increases during the screening period compared to 2% during treatment with active drug in the randomized period. Three patients experienced Grade 1-2 increases in serum creatinine lasting for two weeks or more in the study. One of these patients already had a Grade 1 elevation at baseline. Serum creatinine levels in the other two, which represent 2% of the patients treated with RDEA594, returned to within normal limits after completing the treatment period. There was no dose relationship to these events. Almost all increases in serum creatinine, both pre-treatment and during the dosing period, were observed in patients with high baseline serum urate levels (>10 mg/dL). These patients are known to be at higher risk for renal dysfunction.

Preliminary Safety Results of Phase 2b Monotherapy Study of RDEA594 in the Treatment of Hyperuricemia in Gout Patients

Percent of Patients with Treatment-Related Adverse Events Occurring in More than One Patient

	Treatment Groups

	RDEA594 600mg qd	RDEA594 400mg qd	RDEA594 200mg qd	Placebo
Number of patients	32	33	31	27
Any Adverse Event	16%	15%	7%	15%
Diarrhea	3%	0%	3%	4%
Dyspepsia	0%	6%	0%	0%
Gout flare	9%	3%	0%	4%
Headache	3%	3%	0%	7%

Statements contained in this Form 8-K regarding matters that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding our plans and goals, the expected properties and benefits of RDEA594, RDEA684, RDEA119, RDEA806 and our other compounds and the timing and results of our preclinical, clinical and other studies. Risks that contribute to the uncertain nature of the forward-looking statements include risks related to the outcome of preclinical and clinical studies, risks related to regulatory approvals, delays in commencement of preclinical and clinical studies, costs associated with our drug discovery and development programs, and risks related to the outcome of our business development activities. These and other risks and uncertainties are described more fully in our most recently filed SEC documents, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q, under the headings Risk Factors. All forward-looking statements contained in this Form 8-K speak only as of the date of this Form 8-K. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARDEA BIOSCIENCES, INC.

Date: April 5, 2010

/s/ Christian Waage
Christian Waage
General Counsel