FORM 8-K

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ISIS PHARMACEUTICALS INC

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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): **November 7, 2011**

ISIS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-19125	**33-0336973**
(Commission File No.)	(IRS Employer Identification No.)

2855 Gazelle Court
Carlsbad, CA 92010
(Address of Principal Executive Offices and Zip Code)

Registrant' s telephone number, including area code: **(760) 931-9200**

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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2011, Isis Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company' s financial results for the quarter ended September 30, 2011. In addition to disclosing results that are determined in accordance with Generally Accepted Accounting Principles (GAAP), the Company also discloses pro forma or non-GAAP results of operations, which are adjusted from GAAP to exclude

non-cash compensation related to stock options. The Company is presenting pro forma information excluding the effects of the non-cash compensation expense or benefit because the Company believes it is useful for investors in assessing the Company' s operating results compared to the prior year. A copy of the release is furnished with this report as an exhibit pursuant to "Item 2.02. Results of Operations and Financial Condition" of Form 8-K in accordance with SEC Release Nos. 33-8216 and 34-47583.

The information in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated November 7, 2011.

SIGNATURE

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

ISIS PHARMACEUTICALS, INC.

Dated: November 7, 2011

By: /s/ B. Lynne Parshall

B. LYNNE PARSHALL
Chief Operating Officer,
Chief Financial Officer and Director

INDEX TO EXHIBITS

99.1 Press Release dated November 7, 2011.

Exhibit 99.1

ISIS REPORTS FINANCIAL RESULTS AND HIGHLIGHTS FOR THIRD QUARTER 2011

- **Conference Call Webcast Monday, November 7, 4:30 p.m. ET at www.isispharm.com**

CARLSBAD, Calif., November 7, 2011 - Isis Pharmaceuticals, Inc. (Nasdaq: ISIS) today announced its financial results for the quarter ended September 30, 2011. The Company finished the third quarter of 2011 with a pro forma net operating loss (NOL) of $20.0 million and $44.9 million for the three and nine months ended September 30, 2011, respectively, compared to a pro forma NOL of $6.0 million and $23.1 million for the same periods in 2010. The Company finished the third quarter of 2011 with nearly $365 million in cash.

"Our most notable success this year has been the submission of the Kynamro™ marketing authorization application to the European Medicines Agency. With this submission, we are one step closer to commercializing Kynamro for patients who are at great risk of dying from their cardiovascular disease. Genzyme remains on track to submit the U.S. application for marketing approval in the fourth quarter and is actively preparing to launch Kynamro next year in the U.S. and Europe. Kynamro represents the first major commercial opportunity for Isis, and we are looking forward to its potential launch next year," said B. Lynne Parshall, J.D., Chief Operating Officer, Chief Financial Officer and Secretary of Isis. "Together with Genzyme, we are initiating our next Kynamro study, FOCUS FH, this year, which is intended to support an expansion of the market for Kynamro for severe forms of hypercholesterolemia. We and Genzyme are committed to continuing investments in this novel medicine to make it available to as many patients as appropriate to treat their severe and fatal cardiovascular disease."

Upcoming Key Milestones

- File for marketing approval for Kynamro™ (mipomersen) in the United States in the fourth quarter of 2011 for patients with homozygous Familial Hypercholesterolemia (FH).
- Initiate 12 month clinical study, titled 'evaluating the saFety and atherOgeniC lipoprotein redUction of mipomerSen in FH (FOCUS FH)' , to support additional indications in the United States and Europe, and an alternative dosing regimen.
- Report Phase 1 data on ISIS-FXI$_{Rx}$, ISIS-TTR$_{Rx}$, ISIS-SGLT2$_{Rx}$ and ISIS-APOCIII$_{Rx}$.

Financial Results

On a GAAP basis, Isis reported a loss from operations of $22.3 million and $52.5 million for the three and nine months ended September 30, 2011, respectively, compared to $8.9 million and $32.5 million for the same periods in 2010.

All pro forma amounts referred to in this press release exclude non-cash stock compensation. Please refer to the reconciliation of pro forma and GAAP measures, which is provided later in this release.

Revenue

Revenue for the three and nine months ended September 30, 2011 was $20.7 million and $66.7 million, respectively, compared to $28.6 million and $82.1 million for the same periods in 2010. Isis' revenue fluctuates based on the nature and timing of payments under agreements with the Company' s partners, including license fees, milestone-related payments and other payments. For example, revenue in the first nine months of 2011 included more revenue from GlaxoSmithKline (GSK) compared to 2010 due to the timing of the amortization of the upfront

fee from GSK, which began in the second quarter of 2010. This increase in revenue was offset by less revenue from Bristol-Myers Squibb and no revenue from Alnylam Pharmaceuticals compared to the same period in 2010 because the amortization of upfront fees ended in 2010.

As Isis' drugs advance in development, Isis earns milestone payments, but the timing of these payments fluctuates. For instance, in the first nine months in 2010, Isis recognized as revenue $13 million for milestone payments compared to approximately $6 million in milestone payments in the first nine months of 2011. Since the end of the third quarter, Isis has earned an additional $5 million milestone payment from GSK for designating ISIS-AAT_{Rx} as a development candidate. Because Isis achieved this milestone in October, the Company will recognize revenue from the milestone payment in the fourth quarter of 2011.

Operating Expenses

On a pro forma basis, operating expenses for the three and nine months ended September 30, 2011 were $40.7 million and $111.6 million, respectively, compared to $34.6 million and $105.1 million for the same periods in 2010. Isis' operating expenses in the first nine months of 2011 reflected moderately higher costs associated with Isis' maturing pipeline of drugs as these drugs move forward to more advanced stages of development, including into larger, longer clinical studies. While Isis' share of mipomersen development expenses will be shared equally with Genzyme in 2012, many of the drugs in Isis' pipeline will enter later-stage clinical development. Therefore, Isis expects the Company' s operating expenses to be moderately higher next year.

On a GAAP basis, Isis' operating expenses for the three and nine months ended September 30, 2011 were $43.0 million and $119.2 million, respectively, compared to $37.6 million and $114.6 million for the same periods in 2010.

Net Loss

Isis reported a net loss of $26.9 million and $64.8 million for the three and nine months ended September 30, 2011, respectively, compared to $12.5 million and $47.3 million for the same periods in 2010. Basic and diluted net loss per share for the three and nine months ended September 30, 2011 was $0.27 per share and $0.65 per share, respectively, compared to $0.13 per share and $0.48 per share for the same periods in 2010. In the first nine months of 2011 Isis' net loss increased compared to the same period in 2010 primarily due to a $20.0 million increase in Isis' net operating loss.

Balance Sheet

As of September 30, 2011, Isis had cash, cash equivalents and short-term investments of $364.8 million compared to $472.4 million at December 31, 2010 and had working capital of $293.5 million at September 30, 2011 compared to $377.2 million at December 31, 2010. The decrease in cash and working capital primarily relates to cash used to fund Isis' operations.

Isis' leases on its former research and development facilities expire at the end of 2011. Rather than invest in costly renovations to these facilities, the Company chose to consolidate the majority of its operations in a new leased facility that Biomed Realty Trust, Inc. (BMR) constructed. To make the Company' s move, which happened in August 2011, as efficient as possible, Isis requested access to the new facility prior to the completion of construction. To gain early access, Isis agreed to modify its lease to accept additional responsibility. As a result, accounting rules required Isis to record the cost of the facility as a fixed asset with a corresponding liability. Isis is depreciating the building over its economic life and Isis' rent payments, which begin on January 1, 2012, will decrease the liability over the term of the lease.

Business Highlights

"Marketing approval of Kynamro will be an important milestone for Isis. We are working with Genzyme to continue to enhance Kynamro' s profile and market opportunity. Genzyme recently completed a Special Protocol Assessment, or SPA, with the FDA for the next Kynamro clinical study. The study, FOCUS FH, is designed to achieve three goals: support the expansion of the FH patient population to include severe heterozygous FH in the U.S., support an alternative dosing regimen of three times a week dosing, and support potentially broadening of the

FH indication beyond severe in Europe. We and Genzyme are focused not only on the initial commercial opportunities for Kynamro but also on the longer-term commercial opportunities as we continue to develop this important product," continued Ms. Parshall.

"Although Kynamro is our flagship drug and will be the first systemic antisense drug to reach the market, our pipeline goes well beyond Kynamro. Numerous drugs in our pipeline have demonstrated efficacy in early clinical studies and could represent significant commercial opportunities," continued Ms. Parshall. "The success of our drug discovery and development efforts is evident every quarter as we move our drugs closer to the market. Already this year, we have initiated clinical studies on five drugs, reported encouraging data on our CRP drug and added new drugs into development to treat a wide variety of diseases. We anticipate continuing this steady progress for the rest of the year and into 2012."

"Our business strategy is successful as evidenced by the growth of our partnered pipeline and the substantial cash from our partnering deals. We benefit financially both in the near-term and long-term, from upfront fees, milestone payments, royalties and profit sharing payments and other types of commercial participation. This year, we have earned $13 million in milestones and upfront payments from our partner, GSK, with the expansion of our collaboration to include a sixth target, initiation of clinical development on our TTR drug and identification of the next drug, ISIS-AAT_{Rx}, to move into development. This collaboration provides us with a knowledgeable partner and allows us to quickly expand our severe and rare disease franchise," concluded Ms. Parshall.

Corporate and Drug Development Highlights

- Dr. John Kastelein presented data from the mipomersen open-label extension study at the European Society of Cardiology Congress 2011. These data, in patients who have been treated with mipomersen for greater than one year, demonstrated sustained reductions in all measured atherogenic lipids with a safety profile consistent with the Phase 3 studies.
- Genzyme reached an agreement with the FDA on the design of the FOCUS FH study via a Special Protocol Assessment (SPA).
- Isis initiated Phase 1 studies on ISIS-$GCGR_{Rx}$ and ISIS-$GCCR_{Rx}$.
- Isis added a new drug candidate, ISIS-AAT_{Rx}, to its pipeline in Isis' GSK collaboration. Isis earned a $5 million milestone payment.
- Isis and CHDI renewed their collaboration to discover and develop an antisense drug for the treatment of Huntington' s Disease.
- Isis filed a patent infringement lawsuit against Santaris Pharma based upon Santaris' commercial activities providing antisense drugs and antisense drug discovery services to several pharmaceutical companies.

Conference Call

At 4:30 p.m. Eastern Time today, November 7, Isis will conduct a live webcast conference call to discuss the earnings release and related activities. Interested parties my listen to the call by dialing 888-396-2384 and refer to passcode "ISIS 2011", or access the webcast at www.isispharm.com. A webcast replay will be available for a limited time at the same address.

ABOUT ISIS PHARMACEUTICALS, INC.

Isis is exploiting its leadership position in antisense technology to discover and develop novel drugs for its product pipeline and for its partners. Isis' broad pipeline consists of 25 drugs to treat a wide variety of diseases with an emphasis on cardiovascular, metabolic and severe and rare/neurodegenerative diseases, and cancer. Isis' partner, Genzyme, plans to commercialize Isis' lead product, mipomersen, following regulatory approval, which is expected in 2012. Isis' patents provide strong and extensive protection for its drugs and technology. Additional information about Isis is available at **www.isispharm.com**.

ISIS PHARMACEUTICALS' FORWARD-LOOKING STATEMENT

This press release includes forward-looking statements regarding Isis Pharmaceuticals' financial position and outlook, Isis' business, the planned commercialization of mipomersen, and the therapeutic and commercial potential of Isis' technologies and products in development. Any statement describing Isis' goals, expectations, financial or other projections, intentions or beliefs, including the planned commercialization of mipomersen, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject

to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. Isis' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Isis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Isis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Isis' programs are described in additional detail in Isis' annual report on Form 10-K for the year ended December 31, 2010 and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from the Company.

In this press release, unless the context requires otherwise, "Isis," "Company," "we," "our," and "us" refers to Isis Pharmaceuticals and its subsidiaries, including Regulus Therapeutics Inc., its jointly owned subsidiary.

Isis Pharmaceuticals® is a registered trademark of Isis Pharmaceuticals, Inc. Kynamro™ is a trademark of Genzyme Corporation.

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ISIS PHARMACEUTICALS, INC.
SELECTED FINANCIAL INFORMATION
Condensed Consolidated Statements of Operations
(In Thousands, Except Per Share Data)

	Three months ended, September 30,		Nine months ended, September 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
Revenue:				
Research and development revenue under collaborative agreements	$ 20,189	$ 27,785	$ 64,508	$ 77,484
Licensing and royalty revenue	524	839	2,175	4,569
Total revenue	20,713	28,624	66,683	82,053
Expenses:				
Research and development	39,924	34,716	110,178	105,827
General and administrative	3,105	2,855	8,989	8,724
Total operating expenses	43,029	37,571	119,167	114,551
Loss from operations	(22,316)	(8,947)	(52,484)	(32,498)
Other income (expense):				
Equity in net loss of Regulus Therapeutics Inc.	(386)	(930)	(2,275)	(6,358)
Investment income	575	776	1,896	2,590
Interest expense	(4,773)	(3,338)	(11,624)	(9,835)
Gain (loss) on investments, net	18	(15)	(267)	(1,162)
Loss before income tax expense	(26,882)	(12,454)	(64,754)	(47,263)
Income tax expense	–	–	(11)	(2)
Net loss	$ (26,882)	$ (12,454)	$ (64,765)	$ (47,265)

Basic and diluted net loss per share	$ (0.27)	$ (0.13)	$ (0.65)	$ (0.48)
Shares used in computing basic and diluted net loss per share	99,687	99,196	99,620	99,101

Isis Pharmaceuticals, Inc.
Reconciliation of GAAP to Pro Forma Basis:
Condensed Consolidated Operating Expenses and Loss From Operations
(In Thousands)

	Three months ended, September 30,		Six months ended, September 30,	
	2011	2010	2011	2010
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	$ 43,029	$ 37,571	$ 119,167	$ 114,551
Excluding compensation expense related to stock options	(2,364)	(2,960)	(7,596)	(9,448)
Pro forma operating expenses	$ 40,665	$ 34,611	$ 111,571	$ 105,103
As reported loss from operations according to GAAP	$ (22,316)	$ (8,947)	$ (52,484)	$ (32,498)
Excluding compensation expense related to stock options	(2,364)	(2,960)	(7,596)	(9,448)
Pro forma loss from operations	$ (19,952)	$ (5,987)	$ (44,888)	$ (23,050)

Reconciliation of GAAP to Pro Forma Basis

As illustrated in the Selected Financial Information in this press release, pro forma operating expenses and pro forma loss from operations were adjusted from GAAP to exclude compensation expense related to stock options, which are non-cash. Isis has regularly reported non-GAAP measures for operating expenses and loss from operations as pro forma results. These measures are provided as supplementary information and are not a substitute for financial measures calculated in accordance with GAAP. Isis reports these pro forma results to better enable financial statement users to assess and compare its historical performance and project its future operating results and cash flows. Further, the presentation of Isis' pro forma results is consistent with how Isis' management internally evaluates the performance of its operations.

Isis Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In Thousands)

	September 30, 2011	December 31, 2010
	(unaudited)	
Assets:		
Cash, cash equivalents and short-term investments	$ 364,763	$ 472,353
Other current assets	12,326	10,784
Property, plant and equipment, net	98,019	35,703
Other assets	30,677	31,637

Total assets	$ 505,785	$ 550,477
Liabilities and stockholders' equity:		
Other current liabilities	$ 31,114	$ 31,388
Current portion of deferred contract revenue	52,428	74,502
2 5/8% convertible subordinated notes	139,239	132,895
Long-term obligations, less current portion	73,619	15,867
Investment in Regulus Therapeutics Inc.	3,145	870
Long-term deferred contract revenue	19,415	50,413
Stockholders' equity	186,825	244,542
Total liabilities and stockholders' equity	$ 505,785	$ 550,477

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