EX-99.1 2 dex991.htm PRESS RELEASE

Exhibit 99.1

ISTA Pharmaceuticals Reports Third Quarter 2010 Financial Results

– Net Product Revenues Increased 44% Over Prior-Year Quarter to $42.0 Million –

– ISTA Reaffirms 2010 Guidance, Aims for First Year of Profitability – (excluding warrant charges) –

IRVINE, Calif., Nov. 2, 2010 /PRNewswire-FirstCall/ — ISTA Pharmaceuticals, Inc. (Nasdaq: ISTA), today reported financial results for the quarter ended September 30, 2010. Third quarter 2010 net revenues were $42.0 million, an increase of 31% from the third quarter of 2009. Excluding the recognition of one-time license revenue in the third quarter of 2009, net product revenues increased 44%. Net loss for the third quarter ended September 30, 2010, was $23.5 million, or $0.70 per diluted share, compared to a net loss of $917,000, or $0.03 per diluted share, for the third quarter ended September 30, 2009. Excluding non-cash warrant valuation adjustments and license revenue, net income for the third quarter of 2010 was $2.8 million, or $0.08 per diluted share compared to a loss of $0.4 million, or $0.01 per diluted share in the third quarter of 2009.

“These are exciting times at ISTA. After a strong first half of the year, the third quarter demonstrates that we are on track for an equally strong second half. Not only are we posting revenue growth for all four products and delivering improved operating profitability, we are achieving key new product pipeline milestones,” stated Vicente Anido, Jr., Ph.D., President and Chief Executive Officer of ISTA. “Most recently, we announced the U.S. Food and Drug Administration (FDA) approved BROMDAY™ (bromfenac ophthalmic solution) 0.09% (formerly known as XiDay), our once-daily formulation of bromfenac sodium ophthalmic solution for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction. We believe the introduction of the first and only once-daily non-steroidal anti-inflammatory (NSAID) prescription eye drop will help with treatment compliance and benefit patients recovering from cataract surgery. Our sales force is ready to launch BROMDAY this month. We expect to discontinue the twice-daily XIBROM (bromfenac ophthalmic solution)® 0.09% product in early 2011.”

Continued Anido, “With our newest product pipeline developments, we have proven our ability to extract significant additional value from our core therapeutic compounds, bromfenac and bepotastine. In addition to gaining approvals for BROMDAY and BEPREVE™, we initiated our REMURA™ (bromfenac ophthalmic solution for dry eye) Phase 3 clinical program, plus

released the positive results of our Phase 1/2 bepotastine besilate nasal spray study. Based upon these Phase1/2 results, we plan to submit an Investigational New Drug (IND) Application to the FDA for bepotastine nasal spray to initiate Phase 2 clinical studies before the end of 2010. In addition, we expect to report the results of the REMURA Phase 3 dry eye efficacy study in the middle of 2011. Gaining approval for both product candidates would allow us to participate in significantly larger market segments than those for ISTA's current product offerings. To complement our eye care and allergy franchises, we continue to evaluate acquiring both late-stage drug candidates to add to our pipeline and marketed products to add to our sales portfolio, assets that have the potential to deliver significant value to our stakeholders for years to come."

Net Revenues
(in millions, except percentage data)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
XIBROM	$29.6	$21.4	38%	$ 71.0	$55.1	29%
BEPREVE	3.9	1.2	225%	10.6	1.2	783%
ISTALOL	5.3	5.1	4%	15.0	13.0	15%
VITRASE	3.2	1.4	129%	8.8	4.0	120%
Product sales, net	42.0	29.1	44%	105.4	73.3	44%
License revenue	—	2.9	—	—	3.1	—
Total revenues	$42.0	$32.0	31%	$105.4	$76.4	38%

Net revenues for the third quarter ended September 30, 2010, were $42.0 million, an increase of 31% over the third quarter of 2009. Net revenue growth was driven primarily by strong demand for XIBROM™ and BEPREVE, supported by revenue increases in VITRASE®. In the third quarter of 2009, ISTA recognized $2.9 million of previously deferred license revenue associated with the termination of a supply agreement. Excluding the recognition of deferred license revenue in 2009, net product revenues increased 44% in third quarter 2010 over third quarter 2009.

Gross margin for the third quarter ended September 30, 2010, was 77%, or $32.3 million, as compared to 77%, or $24.7 million, for the same period in 2009. Product gross margin was 77% for the third quarter 2010 and was 75% for the third quarter ended September 30, 2009. Product gross margin improved due to increased sales of our higher gross margin products, XIBROM and BEPREVE.

Research and development (R&D) expenses for the quarter ended September 30, 2010, were $7.9 million, as compared to $6.3 million during the corresponding period of 2009. The increase over the prior-year period was due primarily to the timing, initiation and completion of clinical trials. ISTA initiated its Phase 1/2 clinical program for bepotastine nasal spray in July and its REMURA Phase 3 clinical program for dry eye disease in September.

Selling, general, and administrative, or SG&A, expenses for the quarter ended September 30, 2010, increased to $19.6 million from $13.2 million for the corresponding period in 2009. The increase over the prior-year period reflects the addition of approximately 65 new sales representatives and related corporate new hires earlier in the year, plus promotional activities associated with the launch of BEPREVE.

Operating income for the quarter ended September 30, 2010, was $4.8 million, compared to an operating income of $5.2 million in the corresponding quarter of 2009, which included the license revenue of $2.9 million.

Other expense for the quarters ended September 30, 2010 and 2009, included non-cash valuation losses of $26.3 million and $3.4 million, respectively, as a result of marking common stock warrants to market. Non-cash warrant valuation adjustments are driven primarily by the change in ISTA's stock price quarter over quarter. The non-cash warrant valuation loss decreased reported net loss for the quarter ended September 30, 2010, to $23.5 million, or $0.70 per diluted share. Without the non-cash warrant valuation loss, net income was $2.8 million, or $0.08 per diluted share. In the third quarter of 2009, the non-cash warrant valuation loss for the third quarter 2009 decreased reported net loss to $917,000, or $0.03 per diluted share. Without the non-cash warrant valuation loss, third quarter 2009 net income was $2.5 million, or $0.07 per diluted share.

At September 30, 2010, ISTA had cash of $67.2 million, which included $13 million borrowed under ISTA's revolving line of credit with Silicon Valley Bank. Cash at September 30, 2010, included $16.7 million of reserved royalties on bromfenac.

ISTA Reaffirms 2010 Net Revenues and Net Income Guidance

- ISTA expects its net revenues for 2010 will be approximately in the middle of the $147 million to $165 million range. ISTA expects sales from XIBROM and BROMDAY combined will be at the higher end of the $95 million to $105 million range and anticipates sales from BEPREVE will be approximately $16 million to $20 million.
- ISTA expects its gross margin will be at the higher end of the 74% to 76% range of net revenues.
- ISTA expects R&D expenses will be at the lower end of the 18% to 22% range of net revenues, due to the timing of its clinical programs.
- ISTA expects SG&A expenses will be at the higher end of the 48% to 52% range of net revenues due to launch expenses for BROMDAY. On a dollar basis, ISTA expects SG&A expenses in the fourth quarter of 2010 to be higher than third quarter due to BROMDAY launch costs.
- ISTA's expectations for operating income are unchanged at approximately $8 million to $10 million.
- ISTA expects 2010 to be its first year of profitability with net income of at least $1 million, or earnings per share of $0.02, excluding any non-cash warrant valuation adjustments. As of September 30, 2010, ISTA's fully diluted common shares, including its outstanding shares of common stock plus warrants and stock options on a treasury stock basis were approximately 43 million shares.

- ISTA expects its year-end cash balance to be at least $70 million including amounts borrowed under its revolving credit facility with Silicon Valley Bank. Included in the year-end cash balance estimate is $20 million to $25 million in reserved bromfenac royalties.

ISTA Provides 2011 Net Revenues Outlook

ISTA expects its 2011 net revenues to be in the range of $175 million to $190 million. The company will provide further guidance on 2011 when ISTA reports its 2010 full year results.

Update on Bromfenac Patent Litigation

On August 26, 2010, the U.S. District Court for the Central District of California, stayed the legal action filed in April 2010 by ISTA Pharmaceuticals, Inc. ("ISTA") against Senju Pharmaceutical, Co. Ltd. ("Senju"), in which ISTA seeks, among other remedies, a declaratory judgment that no further royalties are due to Senju related to XIBROM (bromfenac), following a relevant patent's expiration in January 2009. Legal action was stayed pending arbitration upon Senju's request. In September 2010, Senju filed for arbitration. ISTA is currently preparing a response to the International Chamber of Commerce's Court of Arbitration.

There can be no assurances about the duration of the arbitration or appeals that may be filed before, during or after the arbitration process, or how the dispute might be resolved. ISTA has not paid royalties to Senju on XIBROM revenues for 2010 but has been reserving amounts equal to the XIBROM royalties as if owed. ISTA plans to continue reserving for XIBROM and BROMDAY royalties as if owed until the litigation is resolved. As a result, ISTA has not taken into account any potential outcome of this litigation in its 2010 management guidance on expected financial results.

Conference Call

ISTA will host a conference call with a simultaneous webcast today, November 2, 2010, at 4:30 PM Eastern Time, to discuss its third quarter 2010 results. To access the live conference call, U.S. and Canadian participants may dial 866-202-1971; international participants may dial 617-213-8842. The access code for the live call is 22888741. To access the 24-hour audio replay, U.S. and Canadian participants may dial 888-286-8010; international participants may dial 617-801-6888. The access code for the replay is 97091207. This conference call also will be webcast live and archived on ISTA's website for 30 days at http://www.istavision.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.