

10-K 1 d10k.htm ISTA PHARMACEUTICALS, INC. FORM 10-K

[Table of Contents](#)

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

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For Fiscal Year Ended December 31, 2010

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

From the transition period from            to

Commission File Number 000-31255

**ISTA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**33-0511729**  
(I.R.S. Employer  
Identification No.)

**50 Technology Drive, Irvine, California 92618**  
(Address of principal executive offices)

**(949) 788-6000**  
(Registrant's telephone number)

**Securities registered pursuant to Section 12(b) of the Act:**

| <u>Title of Each Class</u>      | <u>Name of Each Exchange on Which Registered</u> |
|---------------------------------|--|
| Common Stock, \$0.001 par value | The NASDAQ Stock Market LLC                      |

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company: in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes  No

As of June 30, 2010, the aggregate market value of the Registrant’s voting stock held by non-affiliates was approximately \$44,319,486.

As of January 31, 2011 there were 33,631,328 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

[Table of Contents](#)

## TABLE OF CONTENTS

[PART I](#)

|  | Page |
|--|------|
| Item 1: <a href="#">Business</a>                   | 1    |
| Item 1A: <a href="#">Risk Factors</a>              | 12   |
| Item 1B: <a href="#">Unresolved Staff Comments</a> | 26   |
| Item 2: <a href="#">Properties</a>                 | 26   |
| Item 3: <a href="#">Legal Proceedings</a>          | 27   |

[PART II](#)

|  |    |
|--|----|
| Item 5: <a href="#">Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a> | 28 |
| Item 6: <a href="#">Selected Financial Data</a>  | 29 |
| Item 7: <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>                        | 30 |
| Item 7A: <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>  | 40 |
| Item 8: <a href="#">Financial Statements and Supplementary Data</a>  | 41 |
| Item 9: <a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>                         | 41 |
| Item 9A: <a href="#">Controls and Procedures</a>   | 41 |
| Item 9B: <a href="#">Other Information</a>   | 43 |

[PART III](#)

|   |    |
|---|----|
| Item 10: <a href="#">Directors, Executive Officers and Corporate Governance</a>   | 43 |
| Item 11: <a href="#">Executive Compensation</a>   | 43 |
| Item 12: <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a> | 43 |
| Item 13: <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>                      | 43 |
| Item 14: <a href="#">Principal Accounting Fees and Services</a>   | 43 |

[PART IV](#)

|   |    |
|---|----|
| Item 15: <a href="#">Exhibits and Financial Statement Schedules</a> | 44 |
|---|----|

[Table of Contents](#)

**ISTA PHARMACEUTICALS, INC.**

**PART I**

References in this Annual Report on Form 10-K to “ISTA”, “we”, “our”, “us”, or the “Company” refer to ISTA Pharmaceuticals, Inc. This Annual Report on Form 10-K contains forward-looking statements based on expectations, estimates and projections as of the date of this filing. Actual results may differ materially from those expressed in forward-looking statements. See Item 7 of Part II – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Forward-Looking Statements.” BROMDAY™, BEPREVE®, ISTALOL®, VITRASE®, XIBROM (bromfenac ophthalmic solution)®, XIBROM™, REMURA™, T-PRED™, ISTA®, ISTA Pharmaceuticals, Inc.® and the ISTA logo are our trademarks, either owned or under license.

We obtained the market data and industry information contained in this Annual Report on Form 10-K from internal surveys, estimates, reports and studies, as appropriate, as well as from market research, publicly available information and industry publications. Although we believe our internal surveys, estimates, reports, studies and market research, as well as industry publications are reliable, we have not independently verified such information, and as such, we do not make any representation as to its accuracy.

**Item 1: Business.**

**Overview**

We are a rapidly growing commercial-stage, multi-specialty pharmaceutical company developing, marketing and selling our own products in the U.S. and Puerto Rico. We are the fourth largest branded prescription eye care business in the U.S. and have an emerging allergy drug franchise. We manufacture our finished good products through third-party contracts, and we in-license or acquire new products and technologies to add to our internal development efforts from time to time. Our products and product candidates seek to treat allergy and serious diseases of the eye and include therapies for ocular inflammation and pain, glaucoma, dry eye and ocular and nasal allergies. The United States, or U.S., prescription markets for 2010 which our therapies seek to address include key segments of the \$6.5 billion ophthalmic pharmaceutical market and the \$2.5 billion nasal allergy market.

We currently have five products available for sale in the U.S. and Puerto Rico: BROMDAY (bromfenac ophthalmic solution) 0.09% for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extractions, BEPREVE (bepotastine besilate ophthalmic solution) 1.5% for the treatment of ocular itching associated with allergic conjunctivitis, ISTALOL (timolol maleate ophthalmic solution) 0.05% for the treatment of glaucoma, VITRASE (hyaluronidase injection) ovine, 200 USP units/ml for use as a spreading agent and XIBROM (bromfenac ophthalmic solution) 0.09% for the treatment of inflammation and pain following cataract surgery. In addition, we have several eye and allergy product candidates in various stages of development, including treatments for dry eye, ocular inflammation and pain and nasal allergies.

We have incurred losses since inception and have a stockholders’ deficit of approximately \$79.1 million (including non-cash valuation warrant adjustments of \$59.6 million) through December 31, 2010.

**Our Products and Pipeline**

The following is a summary of our key products and product candidates:

| <u>Product/Product Candidate</u> | <u>Indication</u>  | <u>Development Status</u> |
|----------------------------------|--|---------------------------|
| BROMDAY (Once-daily)             | Postoperative inflammation and reduction of ocular pain after cataract extractions | Marketed                  |
| BEPREVE                          | Ocular itching associated with allergic conjunctivitis                             | Marketed                  |

|                               |  |  |
|-------------------------------|--|--|
| VITRASE                       | Spreading agent  | Marketed   |
| XIBROM (Twice-daily)          | Ocular inflammation and pain following cataract surgery                            | Marketed, plan to stop product shipments in the first quarter of 2011                                      |
| BROMDAY (lower concentration) | Postoperative inflammation and reduction of ocular pain after cataract extractions | To initiate Phase 3 study 1st half of 2011   |
| REMURA (bromfenac)            | Dry eye syndrome   | Initiated Phase 3 efficacy and short-term safety studies; results expected in 2 <sup>nd</sup> half of 2011 |

# 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.