Form 10-K

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## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington D.C. 20540

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, 2011

or

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

From the transition period from

**Commission File Number 001-35396** 

# 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.)

to

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> Common Stock, \$0.001 par value Name of Each Exchange on Which Registered The NASDAO 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  $\Box$  No  $\boxtimes$ 

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  $\Box$  No  $\boxtimes$ 

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  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this

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chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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.

Large accelerated filer □	Accelerated filer	
Non-accelerated filer $\Box$ (Do not check if a smaller reporting company)	Smaller reporting company	V X

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

As of June 30, 2011, the aggregate market value of the Registrant's voting stock held by non-affiliates was approximately \$218,696,417.

As of January 31, 2012 there were 41,772,441 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE None.

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#### 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 forwardlooking statements. See Item 7 of Part II – "Management's Discussion and Analysis of Financial Condition and Results of Operations." ISTA Pharmaceuticals, Inc. was incorporated as Advanced Corneal Systems, Inc. in California in February 1992 to discover, develop and market new remedies for diseases and conditions of the eye. In March 2000, we changed our name to ISTA Pharmaceuticals, Inc., and we reincorporated in Delaware in August 2000. BROMDAY<sup>TM</sup>, BEPREVE®, ISTALOL®, VITRASE®, XIBROM (bromfenac ophthalmic solution)<sup>®</sup>, XIBROM<sup>TM</sup>, T-PRED<sup>TM</sup>, PROLENSA<sup>TM</sup>, BEPOSONE<sup>TM</sup>, BEPOMAX<sup>TM</sup>, ISTA<sup>®</sup>, ISTA Pharmaceuticals, Inc.<sup>®</sup> 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 United States, or the U.S., and Puerto Rico. We are the third largest branded prescription eye care business in the U.S. and have a growing allergy drug franchise. We have had success in obtaining product approvals for five prescription drugs in six years. We manufacture our finished good products through third-party contracts, and we inlicense 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 U.S. prescription markets for 2011, which our therapies seek to address, include key segments of the \$7.5 billion ophthalmic pharmaceutical market and the \$2.5 billion nasal allergy market.

We currently have four products available for sale in the U.S. and Puerto Rico: once-daily 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, and VITRASE (hyaluronidase injection) ovine, 200 USP units/ml, for use as a spreading agent. At the beginning of 2011, we had one additional product available for sale, twice-daily XIBROM (bromfenac ophthalmic solution) 0.09%, a topical non-steroidal anti-inflammatory formulation of bromfenac for the treatment of ocular inflammation and pain following cataract surgery, or XIBROM. Due to the rapid adoption of BROMDAY, we stopped shipping XIBROM in February 2011. At that time, we anticipated wholesalers would continue to sell XIBROM to pharmacies until their inventories were depleted. As of December 31, 2011, the wholesalers' inventories were depleted. We believe that the conversion of XIBROM to BROMDAY has been well accepted by the markets. 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 \$49.1 million at December 31, 2011.

#### **Recent Business Developments**

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On December 16, 2011, we announced that our Board of Directors, or our Board, had rejected an unsolicited proposal by Valeant Pharmaceuticals International, Inc., or Valeant, to acquire our company for \$6.50 per share in cash, a decision that we reiterated on January 4, 2012, after careful consideration and with the assistance of our financial and legal advisors. On

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December 16, 2011, we also announced that our Board would commence a review of all strategic options available to us in the context of the Board's fiduciary responsibilities and our strategic plans. On January 11, 2012, we received a revised nonbinding proposal from Valeant to acquire our company for \$7.50 per share in cash with a target price of \$8.50 per share in cash, subject to due diligence, which increased proposal Valeant confirmed in a letter to us on January 16, 2012. Valeant withdrew its proposal on January 30, 2012. Our process for review of strategic options is advancing as planned and in an expeditious manner, consistent with our Board's fiduciary responsibilities and our commitment to maximizing shareholder value. Through December 31, 2011, we have incurred \$1.1 million in legal and banking fees to evaluate and respond to Valeant's proposal.

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# DOCKET A L A R M



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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.

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Sync your system to PACER to automate legal marketing.