HALOZYME THERAPEUTICS INC Form 424B3 April 01, 2005

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#### **PROSPECTUS**

#### 23,740,622 Shares

#### HALOZYME THERAPEUTICS, INC.

#### **Common Stock**

This prospectus relates to the sale of up to 23,740,622 shares of our common stock by the selling security holders named in this prospectus. The shares of our common stock offered by the selling security holders through this prospectus are shares previously issued to the selling security holders as well as shares that are issuable upon exercise of warrants. The prices at which the selling security holders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We are not selling any shares of common stock in this offering and therefore we will not receive any of the proceeds from the sale of these shares. We may receive proceeds from the exercise prices of the warrants if any are exercised by the selling security holders.

Our common stock is listed on The American Stock Exchange under the symbol HTI. On March 31, 2005, the last reported sale price for our common stock was \$1.64 per share.

Investing In Our Common Stock Involves Risks. See Risk Factors Beginning On Page 2

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 1, 2005.

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#### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

You should rely only on the information provided or incorporated by reference in this prospectus. We have not authorized anyone to provide you with additional or different information. This document may only be used where it is legal to sell these securities. You should not assume that any information in this prospectus is accurate as of any date other than the date of this prospectus. Information incorporated by reference in this prospectus is accurate only as of the date of the document incorporated by reference. In this prospectus, unless otherwise indicated, the words we, us, and our refer to Halozyme Therapeutics, Inc. and its subsidiaries and do not refer to the selling security holders.

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#### SUMMARY

The following summary highlights selected information from this prospectus and the information incorporated by reference. Because this is a summary, it does not contain all the information about us that may be important to you. You should read the more detailed information in this prospectus and other documents which are incorporated by reference in this prospectus.

Halozyme is a development stage biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the infertility, ophthalmology, and oncology markets.

Our products under development are based on intellectual property covering the family of human enzymes known as hyaluronidases. Hyaluronidases are enzymes (proteins) that break down hyaluronic acid, which is a naturally occurring substance in the human body. Currently, we have no products and all of our potential products are either in the discovery, pre-clinical, pre-NDA or pre-510(k) stage. It may be years, if ever, before we are able to obtain the necessary regulatory approvals necessary to generate meaningful revenue from the sale of these potential products. In addition, we have had operating and net losses each year since inception. We have accumulated a deficit of \$13,071,881 from inception through December 31, 2004.

Our technology is based on recombinant human PH20 (rHuPH20), a human synthetic version of hyaluronidase that degrades hyaluronic acid, a space-filling, gel -like substance that is a major component of tissues throughout the body, such as the skin and eyes. The PH20 enzyme is a naturally occurring enzyme that digests hyaluronic acid to temporarily break down the gel, thereby facilitating the penetration and dispersion of other drugs that are injected in the skin or in the muscle.

Bovine and ovine derived hyaluronidases have been used in multiple therapeutic areas, including in vitro fertilization and ophthalmology, where a FDA-approved bovine version was used as a drug delivery agent to enhance dispersion of local anesthesia for cataract surgery for over 50 years. Despite the multiple potential therapeutic applications for hyaluronidase, there are problems with existing and potential animal derived product offerings.

Deliatroph Pharmaceuticals, Inc., our predecessor company, was founded on February 26, 1998. Our operations to date have been limited to organizing and staffing, acquiring, developing and securing technology and undertaking product development for a limited number of product candidates. As we have not begun principal operations of commercializing a product candidate, the financial statements have been presented as a development stage company.

Our principal executive offices are located at 11588 Sorrento Valley Road, Suite 17, San Diego, California 92121. Our telephone number is (858) 794-8889.

### **The Offering**

In January 2004, we closed a private financing in which we issued 19,046,721 shares of common stock and warrants to purchase 10,461,943 shares of common stock. We agreed to register the common stock issued and issuable in connection with that financing on behalf of the individuals and entities that participated in the financing. Those individuals and entities are referred to in this prospectus as selling security holders. This prospectus covers the sale of the 15,461,760 shares of common stock that have not been previously sold and the remaining 8,278,862 shares that are issuable upon exercise of the warrants. We will not receive any proceeds from sales of the shares that are currently outstanding, but we may receive proceeds from the exercise prices of the warrants if any are exercised by the selling security holders.

Common stock offered by the selling security holders......23,740,622 shares

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#### **RISK FACTORS**

An investment in our common stock involves a high degree of risk. You should carefully consider the following information about these risks, as well as the other information contained or incorporated by reference in this prospectus, before you decide to buy any shares of our common stock. Risks and uncertainties, in addition to those we describe below, that are not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks occur, our business could be harmed, the price of our common stock could decline and you may lose all or part of your investment.

#### **Risks Related To Our Business**

# We have not generated any revenue from product sales to date; we have a history of net losses and negative cash flow, and may never achieve or maintain profitability.

We have not generated any revenue from product sales to date and may never generate significant revenues from future product sales. Even if we do achieve significant revenues from product sales, we expect to incur significant operating losses over the next several years. We have never been profitable, and may never become profitable. Through December 31, 2004, we have incurred aggregate net losses of \$13,071,881.

# We may need to raise funds in the next twelve months, and there can be no assurance that such funds will be available.

During the next twelve months we may need to raise additional capital to complete the steps required to obtain FDA or other regulatory approval for any of our products. If we engage in acquisitions of companies, products, or technology in order to execute our business strategy, we may need to raise additional capital. We may be required to raise additional capital in the future through the public offering of securities, collaborative agreements, private financings and various other equity or debt financings, including calling outstanding warrants to purchase our common stock. Currently, warrants to purchase approximately 11.8 million shares of our common stock are outstanding and this amount of outstanding warrants may make us a less desirable candidate for investment for some potential investors. Approximately 5.9 million of our outstanding warrants contain a call feature that, potentially, will allow us to raise funds from the holders of these warrants. If our common stock closes at a price equal to or greater than \$2.00 per share for twenty consecutive trading days, we have the ability, at our sole discretion, to call warrants exercisable for up to approximately 1,971,000 shares of common stock, provided that we have not exercised a call right in the preceding three months. Upon such a call, the holders of these warrants have thirty days to decide whether to either exercise their warrants at a price of \$1.75 per share or receive \$0.01 from us for each share of common stock that is not exercised. If we need to raise funds in the future and we wish to utilize this call right, we will not be able to exercise the call right if we do not meet the minimum closing price condition and, even if we meet this condition, we cannot be sure of the amounts that will be raised by such a call because some or all warrant holders may decide not to exercise their warrants. Considering our stage of development and the nature of our capital structure, if we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If we are successful in raising additional capital, a substantial number of additional shares will be outstanding and would dilute the ownership interest of our investors.

# If we do not receive and maintain regulatory approvals for our product candidates, we will not be able to commercialize our products, which would substantially impair our ability to generate revenues.

With the exception of the December 2004 receipt of a CE (European Conformity) Mark for Cumulase, none of our product candidates have received regulatory approval from the FDA or from any similar national regulatory agency or authority in any other country in which we intend to do business. Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States. Many other countries including major European countries and Japan have similar requirements.

During September, 2004, we filed a 510(k) application for Cumulase and we intend to file a NDA for Enhanze SC in the first quarter of 2005. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an ovine-derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals,

Inc., with a bovine (bull) hyaluronidase, Amphadase<sup>tm</sup>. The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Enhanze SC would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Enhanze SC; but if the FDA later changes its determination and decides that either or both apply to Enhanze SC, then such a decision could have a material adverse impact on our operations.

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The processes for obtaining FDA approval are extensive, time-consuming and costly, and there is no guarantee that the FDA will approve our recently filed 510(k) application or any NDAs that we intend to file with respect to any of our product candidates, or that the timing of any such approval will be appropriate for our product launch schedule and other business priorities, which are subject to change. We have not currently begun the NDA approval process for any of our potential products, and we may not be successful in obtaining such approvals for any of our potential products.

#### If we are unsuccessful in our clinical trials, we will not receive regulatory approvals for our product candidates.

Clinical testing of pharmaceutical products is also a long, expensive and uncertain process. Even if initial results of pre-clinical studies or clinical trial results are positive, we may obtain different results in later stages of drug development, including failure to show desired safety and efficacy.

The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from obtaining regulatory approval and commercializing the product. FDA approval can be delayed, limited or not granted for many reasons, including, among others:

FDA officials may not find a product candidate safe or effective to merit an approval;

FDA officials may not find that the data from pre-clinical testing and clinical trials justify approval, or they may require additional studies that would make it commercially unattractive to continue pursuit of approval;

the FDA may not approve our manufacturing processes or facilities, or the processes or facilities of our contract manufacturers or raw material suppliers;

the FDA may change its approval policies or adopt new regulations; and

the FDA may approve a product candidate for indications that are narrow or under conditions that place the product at a competitive disadvantage, which may limit our sales and marketing activities or otherwise adversely impact the commercial potential of a product.

If the FDA does not approve our product candidates in a timely fashion on commercially viable terms or we terminate development of any of our product candidates due to difficulties or delays encountered in the regulatory approval process, it will have a material adverse impact on our business and we will be dependent on the development of our other product candidates and/or our ability to successfully acquire other products and technologies.

In addition, we intend to market certain of our products, and perhaps have certain of our products manufactured, in foreign countries. The process of obtaining approvals in foreign countries is subject to delay and failure for similar reasons.

# If our product candidates are approved by the FDA but do not gain market acceptance, our business will suffer because we may not be able to fund future operations.

Assuming that we obtain the necessary regulatory approvals, a number of factors may affect the market acceptance of any of our existing product candidates or any other products we develop or acquire in the future, including, among others:

the price of our products relative to other therapies for the same or similar treatments;

the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their prescribed treatments;

our ability to fund our sales and marketing efforts;

the effectiveness of our sales and marketing efforts; and

the introduction of generic competitors.

We have never successfully marketed any products, and we may not be successful in marketing and promoting our existing product candidates or any other products we develop or acquire in the future.

In addition, our ability to market and promote our product candidates will be restricted to the labels approved by the FDA. If the approved labels are restrictive, our sales and marketing efforts, as well as market acceptance and the commercial potential of our products may be negatively affected.

If our products do not gain market acceptance, we may not be able to fund future operations, including the development or acquisition of new product candidates and/or our sales and marketing efforts for our approved products, which would cause our business to suffer.

# If we are unable to sufficiently develop our sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize products.

We are currently in the process of developing our sales, marketing and distribution capabilities. However, our current capabilities in these areas are very limited. In order to commercialize any products successfully, we must internally develop substantial sales, marketing and distribution capabilities, or establish collaborations or other arrangements with third parties to perform these services. We do not have extensive experience in these areas, and we may not be able to establish adequate in-house sales, marketing and distribution capabilities or engage and effectively manage relationships with third parties to perform any or all of such services. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, whose efforts may not be successful.

# If we have problems with our sole contract manufacturer, our product development and commercialization efforts for our product candidates could be delayed or stopped.

We have signed a commercial supply agreement with Avid Bioservices Incorporated (Avid), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical use. Avid will produce the active pharmaceutical ingredient under current good manufacturing practices for commercial scale production and will provide support for chemistry, manufacturing and controls sections for FDA regulatory filings. The active pharmaceutical ingredient is used in Enhanze SC, which may require a pre-approval inspection. If Avid fails this pre-approval inspection, it could have a material adverse effect on our business. We have not established and may not be able to establish arrangements with additional manufacturers for these ingredients or products should the existing supplies become unavailable or in the event that our sole contract manufacturer is unable to adequately perform its responsibilities. Difficulties in our relationship with Avid or delays or interruptions in Avid s supply of its requirements could limit or stop our ability to provide sufficient quantities of our products, on a timely basis, for clinical trials and, if our products are approved, could limit or stop commercial sales, which would have a material adverse effect on our business and financial condition.

# If we have problems with the third parties that prepare, package and fill/ finish our product candidates for distribution, our product development and commercialization efforts for these candidates could be delayed or stopped.

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, package and fill/finish the products prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are economically acceptable to us, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a third party to fill/finish and package Cumulase. In addition, we currently utilize a third party to fill/finish and package Enhanze SC under an agreement that is terminable by either party, but we are currently negotiating with this third party on a long-term agreement. If we fail to finalize an agreement with this third party, the clinical trial progress, and potential commercialization of Enhanze SC, will likely be delayed.

# Our inability to attract, hire and retain key management and scientific personnel, and to recruit qualified independent directors, could negatively affect our business.

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. In addition, we also rely on the expertise and guidance of independent directors to develop business strategies and to guide our execution of these strategies. Due to changes in the regulatory environment for public companies over the past few years, the demand for independent directors has increased and it may be difficult for us, due to competition from both like-sized and larger companies, to recruit qualified independent directors.

Furthermore, if we were to lose key management personnel, particularly Jonathan Lim, MD, our chief executive officer, or Gregory Frost, PhD, our chief scientific officer, then we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained. For example, Dr. Frost has been with our Company from soon after its inception, and he possesses a substantial amount of knowledge about our development efforts. If we were to lose his services, we would experience delays in meeting our product development schedules. We have not entered into employment agreements with any of our employees or officers, including Dr. Lim and Dr. Frost. We do not have key man life insurance policies on the lives of any of our employees, including Dr. Lim and Dr. Frost.

# Future sales of shares of our common stock, including sales of shares issued in our most recent financings, may negatively affect our stock price.

As a result of our January 2004 private financing transaction, we issued 19,046,721 shares of common stock to certain private investors. In connection with this transaction we also issued warrants to the private investors for the purchase of 10,461,943 shares of common stock at purchase prices ranging from \$0.77 to \$1.75 per share. Currently, 8.3 million shares of common stock remain issuable upon exercise of these warrants. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise. We filed a registration statement on Form SB-2 (Registration No. 333-114776), which was declared effective on August 12, 2004, covering the 29,508,664 shares issued to the private investors and issuable upon exercise of the warrants.

As a result of our October 2004 financing transaction, we issued 7,925,715 shares of common stock to certain institutional and accredited investors for \$13.9 million in gross proceeds. In connection with this transaction, we also issued warrants for the purchase of 2,609,542 shares of common stock. We filed a registration statement on Form S-3 (Registration No. 333-120448), which was declared effective on November 26, 2004, covering the 10,535,257 shares issued to the private investors and issuable upon exercise of the warrants. In the future, we may issue additional options, warrants or other derivative securities convertible into Halozyme common stock.

Sales of substantial amounts of shares of our common stock, or even the potential for such sales through the exercise of warrants, could lower the market price of our common stock and impair the Company s ability to raise capital through the sale of equity securities.

### Our stock price is subject to significant volatility.

Our stock price is subject to significant volatility. Overall market conditions, in addition to other risks and uncertainties described in this section and elsewhere in this report, may cause the market price of our common stock to fall. We participate in a highly dynamic industry, which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low stock prices during 2004 were \$4.75 and \$0.02, respectively. Fluctuations in the price of our common stock may be exacerbated by conditions in the healthcare and technology industry segments or conditions in the financial markets generally.

# Recent trading in our stock has been limited, so investors may not be able to sell as much stock as they want to at prevailing market prices.

During the last ninety days, our average daily trading volume was approximately 164,000 shares. If limited trading in our stock continues, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

#### Our decision to redeem outstanding warrants may drive down the market price of our stock.

As discussed above in the Risk Related to Our Business titled *We may need to raise funds in the next twelve months, and there can be no assurance that such funds will be available* we may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 5.9 million shares of common stock. The redemption price for these warrants is \$0.01 per share, but the warrant holders have the opportunity to exercise their warrants prior to redemption at the price of \$1.75 per share. If we decide to redeem any portion of our outstanding warrants in the future, some selling security holders may choose to sell outstanding shares of common stock in order to finance the exercise of the warrants prior to their redemption. This pattern of selling may result in a reduction of our common stock s market price.

#### **Risks Related To Our Industry**

# Compliance with the extensive government regulations to which we are subject is expensive and time consuming, and may result in the delay or cancellation of product sales, introductions or modifications.

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including Halozyme, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and to a lesser extent by the U.S. Drug Enforcement Administration (DEA), and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, Halozyme and its contract suppliers and manufacturers are subject to periodic inspection of its or their respective facilities, procedures and operations and/or the testing of products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that Halozyme and its contract suppliers and manufacturers are in compliance with all applicable regulations. The FDA also conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems, or our contract suppliers and manufacturers processes, are in compliance with current good manufacturing practices and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals, including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet.

We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping our products. Consequently, there is always a risk that the FDA or other applicable governmental authorities will not approve our products, or will take post-approval action limiting or revoking our ability to sell our products, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans or results of operations.

# Our suppliers and sole manufacturer are subject to regulation by the FDA and other agencies, and if they do not meet their commitments, we would have to find substitute suppliers or manufacturers, which could delay the supply of our products to market.

Regulatory requirements applicable to pharmaceutical products make the substitution of suppliers and manufacturers costly and time consuming. We have no internal manufacturing capabilities and are, and expect

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to be in the future, entirely dependent on contract manufacturers and suppliers for the manufacture of our products and for their active and other ingredients. The disqualification of these manufacturers and suppliers through their failure to comply with regulatory requirements could negatively impact our business because the delays and costs in obtaining and qualifying alternate suppliers (if such alternative suppliers are available, which we cannot assure) could delay clinical trials or otherwise inhibit our ability to bring approved products to market, which would have a material adverse affect on our business and financial condition.

# We may be required to initiate or defend against legal proceedings related to intellectual property rights, which may result in substantial expense, delay and/or cessation of the development and commercialization of our products.

We rely on patents to protect our intellectual property rights. The strength of this protection, however, is uncertain. For example, it is not certain that:

our patents and pending patent applications cover products and/or technology that we invented first;

we were the first to file patent applications for these inventions;

others will not independently develop similar or alternative technologies or duplicate our technologies;

any of our pending patent applications will result in issued patents; and

any of our issued patents, or patent pending applications that result in issued patents, will be held valid and infringed in the event the patents are asserted against others.

We currently own or license several U.S. patents and also have pending patent applications. There can be no assurance that our existing patents, or any patents issued to us as a result of such applications, will provide a basis for commercially viable products, will provide us with any competitive advantages, or will not face third-party challenges or be the subject of further proceedings limiting their scope or enforceability.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. In addition, costly litigation could be necessary to protect our patent position. We also rely on trademarks to protect the names of our products. These trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect with confidentiality agreements with employees, consultants and others with whom we discuss our business. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and we might not be able to resolve these disputes in our favor.

In addition to protecting our own intellectual property rights, third parties may assert patent, trademark or copyright infringement or other intellectual property claims against us based on what they believe are their own intellectual property rights. While we have not ever been and are currently not involved in any litigation, in the event we become involved, we may be required to pay substantial damages, including but not limited to treble damages, for past infringement if it is ultimately determined that our products infringe a third party s intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management s attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights. If such a license is available at all, it may require us to pay substantial royalties or other fees.

#### Future acquisitions could disrupt our business and harm our financial condition.

In order to remain competitive, we may decide to acquire additional businesses, products and technologies. As we have limited experience in evaluating and completing acquisitions, our ability as an organization to

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make such acquisitions is unproven. Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following:

we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;

we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;

certain acquisitions may disrupt our relationship with existing customers who are competitive with the acquired business;

acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;

an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;

acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and

key personnel of an acquired company may decide not to work for us.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results. We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market will not view such acquisitions positively.

#### If third-party reimbursement is not available, our products may not be accepted in the market.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health insurers, managed care organizations and other healthcare providers.

Third-party payers are increasingly attempting to limit both the coverage and the level of reimbursement of new drug products to contain costs. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. If we succeed in bringing one or more of our product candidates to market, third-party payers may not establish adequate levels of reimbursement for our products, which could limit their market acceptance and result in a material adverse effect on our financial condition.

# We face intense competition and rapid technological change that could result in the development of products by others that are superior to the products we are developing.

We have numerous competitors in the United States and abroad, including, among others, major pharmaceutical and specialized biotechnology firms, universities and other research institutions that may be developing competing products. Such competitors include Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc. (ISTA), and Allergan, Inc., among others. These competitors may develop technologies and products that are more effective or less costly than our current or future product candidates or that could render our technologies and product candidates obsolete or noncompetitive. Many of these competitors have substantially more resources and product development, manufacturing and marketing experience and capabilities than we do. In addition, many of our competitors have

significantly greater experience than we do in undertaking pre-clinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an

ovine-derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase<sup>tm</sup>. The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Enhanze SC would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Enhanze SC; but if the FDA later changes its determination and decides that either or both apply to Enhanze SC, then such a decision could have a material adverse impact on our operations.

# We are exposed to product liability claims, and insurance against these claims may not be available to us on reasonable terms or at all.

We might incur substantial liability in connection with clinical trials or the sale of our products. Product liability insurance is expensive and in the future may not be available on commercially acceptable terms, or at all. We currently carry a limited amount of product liability insurance. A successful claim or claims brought against us in excess of our insurance coverage could materially harm our business and financial condition. *We may have difficulty implementing in a timely manner the internal controls over financial reporting necessary to allow our management to report on the effectiveness of our internal controls over financial reporting, and we may incur substantial costs in order to comply with the requirements of the Sarbanes-Oxley Act of 2002.* 

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to furnish a report of management s assessment of the effectiveness of our internal controls over financial reporting as part of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006. Our registered public accountant will then be required to attest to, and report on, our assessment. In order to issue our report, our management must document both the design for our internal controls over financial reporting and the testing processes that support management s evaluation and conclusion. There can be no assurance that we will be able to complete the work necessary for our management to issue its management report in a timely manner, or that management will be able to report that our internal controls over financial reporting are effective.

#### **USE OF PROCEEDS**

We will not receive proceeds from the sale of shares under this prospectus, but we did receive consideration from the selling security holders at the time they purchased the shares. We may receive proceeds from the exercise price of the warrants if they are exercised by the selling security holders. Assuming the exercise of all the selling security holders warrants, we would receive gross proceeds of approximately \$12,160,000. We intend to use any proceeds from the exercise of the warrants for working capital and general corporate purposes.

#### SELLING SECURITY HOLDERS

The shares are being offered by certain selling security holders. The selling security holders may from time to time offer and sell pursuant to this prospectus up to an aggregate of 23,740,622 shares of our common stock now owned by them or issuable to them upon the exercise of warrants. The selling security holders may, from time to time, offer and sell any or all of the shares that are registered under this prospectus. Because the selling security holders are not obligated to sell their shares, and because the selling security holders may also acquire publicly traded shares of our common stock, we cannot estimate how many shares the selling security holders will own after the offering.

Except for Mark Wilson, who currently serves as our Vice President of Business Development, none of the selling security holders has ever held an office, been a director or had any other material relationship with Halozyme or its predecessor company.

Pursuant to the stock purchase agreements with the selling security holders, all expenses incurred with respect to the registration of the common stock will be borne by us, but we will not be obligated to pay any underwriting fees, discounts, commissions or other expenses incurred by them in connection with the sale of such shares.

The following table sets forth, with respect to the selling security holders: (i) the number of shares of common stock covered by this prospectus that are issuable upon exercise of the warrants, (iii) the total shares of common stock covered by this prospectus, (iv) the total number of shares of common stock beneficially owned but not covered by this prospectus, (v) the total number of shares of common stock beneficially owned by such selling security holders as of February 1, 2005, and (vi) the percentage of shares of common stock beneficially owned as of February 1, 2005, based upon approximately 49.4 million shares of common stock outstanding as of February 1, 2005 (each selling security holder s beneficial ownership total reflects shares owned beneficially as of August 12, 2004 as adjusted by (i) warrant exercises and redemptions and (ii) the sale of registered shares from that date through February 1, 2005, and such totals do not include any shares that were purchased or sold on the open market unless such purchases and sales were reported in public filings made with the Securities and Exchange Commission).

## SELLING SECURITY HOLDERS

		Shares of Common Stock	Total Shares of	Shares of Common		
	Shares of Common	Issuable Upon	Common Stock Equivalents	Stock Beneficially Owned But	Total Shares of Common	Total
	Stock Being	Exercise of	Being	NOT Being	Stock Beneficially	Beneficial
Security Holders	Registered	Warrants	Registered	Registered	•	)wnership%
Adam K. Stern		15,000	15,000		15,000	0.03%
Anthony Salandra	70,673	59,423	130,096		130,096	0.26%
Arianna Sheree Lynch	2,407		2,407		2,407	0.00%
Asia Pacific Imports	56,250	18,750	75,000		75,000	0.15%
Autry Qualified Interest						
Trust	225,000	75,000	300,000		300,000	0.61%
Baybridge Capital Corp.	46,856	140,569	187,425		187,425	0.38%
BioGrowth, Inc.	259,205	140,569	399,774		399,774	0.80%
Bonanza Master Fund,						
LTD	675,000	225,000	900,000	1,114,286	2,014,286	4.06%
Brean Murray & Co. Inc.	50,071	273,213	323,284		323,284	0.65%
Cantonal Corporation	103,001	112,500	215,501	45,000	260,501	0.53%
Centrum Bank AG	125,000	75,000	200,000		200,000	0.40%
Cimarron Biomedical						
Investors	225,000	75,000	300,000		300,000	0.61%
Cindy Ullman	7,500		7,500		7,500	0.02%
Colleen Paffie	8,800		8,800		8,800	0.02%
Curtis Leahy	395,000		395,000		395,000	0.80%
Darren Blanton	592,788	412,788	1,005,576	334,286	1,339,862	2.69%
David Hochman		3,750	3,750		3,750	0.01%
Dr. Donald Cramer	2,500	938	3,438		3,438	0.01%
Dr. Leonard Makowka	11,250	3,750	15,000		15,000	0.03%
Equine Consultants Ltd.	107,500		107,500		107,500	0.22%
Erietta Papakosta		37,500	37,500		37,500	0.08%
Forest Hill Select Fund,						
LP	360,000	120,000	480,000		480,000	0.97%
Franklin H. Nyi	90,000	30,000	120,000		120,000	0.24%
Garfield Associates, LLC	2,500	7,500	10,000		10,000	0.02%
Gene Salkind, MD	180,000	60,000	240,000	150,000	390,000	0.79%
Grant Bettingen, Inc.	41,298		41,298		41,298	0.08%
Harvest International	107,596	107,596	215,192		215,192	0.44%
Harvey Anderson		53,798	53,798		53,798	0.11%
Harvey Grossman	8,800		8,800		8,800	0.02%
Henri Talerman	80,000	30,000	110,000		110,000	0.22%
Hyde Family Trust	90,000	30,000	120,000		120,000	0.24%
Jacqueline Autry	45,000	15,000	60,000		60,000	0.12%
Janelle Noelle Lynch	2,407		2,407		2,407	0.00%
	30,000		30,000		30,000	0.06%

Jardine, McManus,							
Murphy & Moore, LTD							
Jason Daggett	37,905		37,905	37,905	0.08%		
Jeffrey Geddes	8,800		8,800	8,800	0.02%		
Jerome Morgan	9,900	3,300	13,200	13,200	0.03%		
Jesse Grossman	1,296,795	500,913	1,797,708	1,797,708	3.61%		
Jesse Grossman							
Accountancy Corp.							
Retirement Trust	474,890	160,078	634,968	634,968	1.28%		
John Paul DeJoria	80,000	30,000	110,000	110,000	0.22%		
John S. Lemak	90,000	30,000	120,000	120,000	0.24%		
Jonathan Spanier	1,209,423	523,313	1,732,736	1,732,736	3.48%		
Jonathan Spanier							
Custodian for Esme							
Spanier under CUTMA,							
age 21	50,000		50,000	50,000	0.10%		
Keith Granirer	7,500	2,813	10,313	10,313	0.02%		
Ken Rickel	473,942	301,442	775,384	775,384	1.56%		
Ken Y. Leung	80,000	30,000	110,000	110,000	0.22%		
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	CI E	Shares of Common Stock	Total Shares of	Shares of Common	T. ( ) ()	
	Shares of Common	Issuable Upon	Common Stock Equivalents	Stock Beneficially Owned But	Total Shares of Common	Total
	Stock Being	Exercise of	Being	NOT Being	Stock Beneficially	Beneficial
<b>Security Holders</b> Kerry McVey	Registered	Warrants 53,798	<b>Registered</b> 53,798	Registered	e	<b>)wnership%</b> 0.11%
Kimberly		55,170	55,170		55,190	0.1170
Craig Woodworth	10,000		10,000		10,000	0.02%
Kingsbridge Capital	18,750	56,250	75,000		75,000	0.15%
Laura Stone	8,800	3,300	12,100	1,315	13,415	0.03%
Lawrence Diamant	3,938	1,312	5,250	1,010	5,250	0.01%
Lincoln Associates, LLC	2,500	7,500	10,000		10,000	0.02%
Linda May Stone	41,500	15,000	56,500	100	56,600	0.11%
Lore E. Stone	27,000	9,000	36,000		36,000	0.07%
Louis F. Burke PC						
Retirement Trust	20,000	7,500	27,500		27,500	0.06%
Louis Spanier	25,000		25,000		25,000	0.05%
Mark Emalfarb Custodian						
for Ashley Emalfarb	9,000	3,000	12,000		12,000	0.02%
Mark Emalfarb Custodian						
for Hailey Emalfarb	9,000	3,000	12,000		12,000	0.02%
Mark Wilson	50,000		50,000		50,000	0.10%
Matthew Markin		30,000	30,000	18,500	48,500	0.10%
Michael Clofine		53,798	53,798		53,798	0.11%
Michael P. Marcus	20,000	30,000	50,000		50,000	0.10%
Michael Stone	629,394	317,394	946,788		946,788	1.91%
Nadine Smith	251,592	157,197	408,789		408,789	0.83%
Odyssey Holdings Ltd.	345,905	140,569	486,474		486,474	1.00%
Oppenheimer & Co. Inc.						
Custodian for Jonathan						
Spanier IRA Rollover	474,890	158,677	633,567		633,567	1.28%
Patricia Fox	8,800		8,800		8,800	0.02%
Paul Geddes	8,800		8,800		8,800	0.02%
Paul Rosenberg	53,798	53,798	107,596		107,596	0.22%
Paula Rubino	8,800		8,800		8,800	0.02%
Peter Geddes	1,579,118	553,319	2,132,437	85,500	2,217,937	4.45%
Peter Geddes Custodian						
for Avery Geddes under	20.000		20.000		20.000	0.040
CUTMA, age 21	20,000		20,000		20,000	0.04%
Peter Geddes Custodian						
for Campbell Geddes	50.000	10 750	60 750		(0.7E)	0 1 4 07
under CUTMA, age 21	50,000	18,750	68,750 68,750		68,750 68,750	0.14%
Peter Geddes Custodian	50,000	18,750	68,750		68,750	0.14%
for Lily Geddes under						

CUTMA, age 21						
Peter Geddes Custodian						
for Zachary Geddes under						
CUTMA, age 21	20,000		20,000		20,000	0.04%
Peter Graffman	78,125	9,375	87,500		87,500	0.18%
Peter Kosa	92,500	37,500	130,000		130,000	0.26%
Ram Trading, Ltd.	233,350	375,000	608,350		608,350	1.23%
Richard Genovese	1,343,906	734,892	2,078,798	400,027	2,478,825	4.96%
Roth Capital Partners,						
LLC	75,000	225,000	300,000		300,000	0.61%
Sandor Capital Master						
Fund, L.P.	281,250	93,750	375,000		375,000	0.76%
Sandy Geddes	8,800		8,800		8,800	0.02%
Sean Fitzpatrick		9,375	9,375		9,375	0.02%
Sean Dignan	2,000		2,000		2,000	0.00%
Shai Z. Stern		45,000	45,000	50,000	95,000	0.19%
Spectrum Advisors, Ltd.	345,096	145,096	490,192	3,000	493,192	1.00%
Stephanie Spanier	50,000		50,000		50,000	0.10%
Steven S. Vender	45,000	16,875	61,875	5,000	66,875	0.14%
TBG America Inc.	80,000	30,000	110,000		110,000	0.22%
The Ward Family						
Foundation	135,000	45,000	180,000		180,000	0.36%
University Finance, Inc.	264,289	678,550	942,839		942,839	1.90%
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		Shares of Common	Total Shares of	Shares of Common		
	Shares of Common	Stock Issuable Upon	Common Stock Equivalents	Stock Beneficially Owned But	Total Shares of Common	Total
	Stock Being	Exercise of	Being	NOT Being	Stock	Beneficial
	<b>D</b> • 4 1				Beneficially	
Security Holders	Registered	Warrants	Registered	Registered		Ownership%
Vega Investments Inc.	234,000	78,000	312,000		312,000	0.63%
Vertical Ventures, LLC		75,000	75,000		75,000	0.15%
Vitel Ventures Corp.	410,004	246,535	656,539	32,248	688,787	1.39%
Whitney & Clarkia						
Wilson Trust	50,000		50,000	50,000	100,000	0.20%
William F. Miller III	121,298	22,500	143,798		143,798	0.29%
Winnie Huang	45,000	15,000	60,000		60,000	0.12%
Total	15,461,760	8,278,862	23,740,622	2,289,262	26,029,884	45.41%

Subject to applicable exceptions set forth by the Securities and Exchange Commission, transferees, pledgees, donees or successors to the selling security holders named in the prospectus may not offer and sell securities pursuant to the prospectus unless we supplement or amend the prospectus to reflect the required information concerning such transferees, pledgees, donees or successors.

#### PLAN OF DISTRIBUTION

The selling security holders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell all or any part of their shares of common stock offered hereby on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling security holders may use any one or more of the following methods when selling shares:

· ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

 $\cdot$  block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

· purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

 $\cdot$  an exchange distribution in accordance with the rules of the applicable exchange;

· privately negotiated transactions;

 $\cdot$  short sales;

 $\cdot$  broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;

 $\cdot$  a combination of any such methods of sale; and

 $\cdot$  any other method permitted pursuant to applicable law.

The selling security holders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. The selling security holders may also engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities, and may sell or deliver shares in connection with these trades. The selling security holders may pledge their shares to their brokers under the margin provisions of customer agreements. If a selling security holder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

Broker-dealers engaged by the selling security holders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling security holders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling security holders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling security holders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. Any selling security holders that are broker-dealers or broker-dealer affiliates will be deemed to be underwriters within the meaning of the Securities Act in connection with any sales of the shares by them. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Of the selling security holders Brean Murray & Co.; Grant Bettinger, Inc.; and Roth Capital Partners, LLC are each broker-dealers. Additionally, Curtis Leahy, who is a registered representative of Grant Bettinger, Inc. is an affiliate of broker-dealers.

Because selling security holders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the selling security holders will be subject to the prospectus delivery requirements of the Securities Act and the rules promulgated thereunder. We have informed the selling security holders that the anti-manipulative provisions of Regulation M promulgated under the Exchange Act may apply to their sales in the market.

#### **Table of Contents**

We are required to pay all fees and expenses (excluding selling expenses) incident to the registration of the shares being registered herein, including fees and disbursements of counsel to the selling security holders. We have agreed to indemnify certain of the selling security holders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

After being notified by a selling security holder that any material arrangement has been entered into with a broker-dealer or underwriter for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker, dealer or underwriter, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling security holder and of the participating broker-dealer(s) or underwriter(s), (ii) the number of shares involved, (iii) the price at which such shares were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s) or underwriter(s), where applicable, (v) that such broker-dealer(s) or underwriter(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus and (vi) other facts material to the transaction. Individuals and entities who receive shares from the selling security holders as a gift or in connection with a pledge may sell up to 500 of such shares pursuant to this prospectus.

#### LEGAL MATTERS

The validity of the shares of common stock being sold in this offering and other legal matters relating to the offering has been passed upon for us by Hale Lane Peek Dennison and Howard, Reno, Nevada.

#### **EXPERTS**

The consolidated financial statements of Halozyme Therapeutics, Inc. as of December 31, 2004, and for each of the years in the two-year period ended December 31, 2004, as set forth in our filing on form 10-KSB with the Securities and Exchange Commission on March 11, 2005, have been incorporated by reference herein and in the registration statement in reliance upon the report of Cacciamatta Accountancy Corporation, independent auditors, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. We file proxy statements and annual, quarterly and special reports and other information with the SEC. You can inspect and copy the registration statement as well as the reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 450 Fifth Street, N.W., Washington, D.C. You can call the SEC at 1-800-SEC-0330 for further information about the public reference rooms. We are also required to file electronic versions of these documents with the SEC, which may be accessed from the SEC s Internet site at http://www.sec.gov or at our website http://www.halozyme.com.

The SEC requires us to incorporate by reference certain of our publicly-filed documents into this prospectus, which means that information included in those documents is considered part of this prospectus. Information that we file with the SEC after the effective date of this prospectus will automatically update and supersede this information, as well as the other information contained in this prospectus. In addition, we also incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of the filing of this registration statement, until such time as the effectiveness of this registration statement is terminated.

The following documents filed with the SEC are incorporated by reference in this prospectus:

- 1. Our Annual Report on Form 10-KSB for the year ended December 31, 2004, as amended on the Form 10-KSB/A filed on March 29, 2005.
- 2. Our Report on Form 8-K dated February 22, 2005.
- 3. Our Report on Form 8-K dated March 28, 2005.
- 4. Our Report on Form 8-K dated March 30, 2005.
- 5. Our registration statement on Form SB-2/A, file No. 333-114776, including the description of our common stock contained therein, filed with the SEC on July 23, 2004.
- 6. All of the filings pursuant to the Securities Exchange Act that we may make prior to the effectiveness of this registration statement, and prior to the termination of the offering contemplated by this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference. You should direct any requests for documents to David Ramsay, Chief Financial Officer, 11588 Sorrento Valley Road, Suite 17, San Diego, California 92121, telephone: (858) 794-8889.

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### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as anticipates, estimates, plans. projects, continuing, ongoing, expects. manageme we believe. we intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors listed under the section entitled Risk Factors.

Because the factors referred to in the preceding sentence could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

### 23,740,622 SHARES OF

### **COMMON STOCK**

### HALOZYME THERAPEUTICS, INC.

PROSPECTUS April 1, 2005