Sarepta Therapeutics, Inc.
Form 10-K
March 15, 2013
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2012**

**Or**

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 Or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**

**Commission file number: 001-14895**

# Sarepta Therapeutics, Inc.

**(Exact name of registrant as specified in its charter)**

| **Oregon** | **93-0797222** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**215 First Street**

**Suite 007**

**Cambridge, MA** **02142**
**(Address of principal executive offices)** **(Zip Code)**
**Registrant s telephone number, including area code: (857) 242-3700**

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

| **Tile of Each Class** | **Name of Exchange on Which Registered** |
|---|---|
| **Common Stock, $0.0001 par value** | **The NASDAQ Stock Market LLC** |
| | **(The NASDAQ Global Market)** |

**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 x 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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, 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 x No ¨

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 the 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 | x |
| 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 in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2012 was approximately $84,275,000.

The number of outstanding shares of the registrant s common stock as of the close of business on February 28, 2013 was 31,831,212.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant has incorporated into Part III of this Annual Report on Form 10-K, by reference, portions of its definitive Proxy Statement for its 2013 annual meeting.

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**Sarepta Therapeutics, Inc.**

**FORM 10-K INDEX**

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**PART I**

**Item 1. Business.**

**Forward-Looking Information**

*This Annual Report on Form 10-K, including the Management s Discussion and Analysis of Financial Condition and Results of Operations section in Item 7, and other materials accompanying this Annual Report on Form 10-K contain forward-looking statements or incorporate by reference forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may, seek and other similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other forward-looking information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:*

*our expectations regarding the development and clinical benefits of our product candidates;*

*the results of our research and development efforts and the efficacy of our PMO-based chemistries and other RNA-based technology;*

*our expectations regarding our ability to become a leading developer and marketer of RNA-based therapeutics;*

*our expectations regarding the results of preclinical and clinical testing of our product candidates;*

*the efficacy, potency and utility of our product candidates in the treatment of rare and infectious diseases, and their potential to treat a broad number of human diseases;*

*our expectations regarding initiating a pivotal clinical trial for eteplirsen by the end of 2013 and commencing dosing in this trial early 2014;*

*our ability to submit IND filings for DMD candidates beyond eteplirsen;*

*our ability to initiate Phase I multiple ascending dose studies for AVI-7288 for treatment of the Marburg virus in 2013;*

*the receipt of any required approval from the U.S. Food and Drug Administration, or the FDA, or other regulatory approval for our products;*

*the potential for our product candidates to qualify for accelerated approval, as breakthrough therapies or as orphan drugs;*

*the potential for any filings or applications by us for accelerated approval or other designations to be accepted or granted by the FDA;*

*the effect of regulation by the FDA and other agencies;*

*our intention to introduce new products;*

*our expectations regarding the markets, pricing or reimbursement for our products;*

*acceptance of our products, if introduced, in the marketplace;*

*the impact of competitive products, product development, commercialization and technological difficulties;*

*our expectations regarding our ability to commercialize eteplirsen with a relatively small sales force, if eteplirsen is approved for commercial sale;*

*our expectations regarding partnering opportunities and other strategic transactions;*

*our ability to increase the scale of our manufacturing to provide our product to patients in larger scale clinical trials or in potential commercial quantities;*

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*our ability to operate our business without infringing the intellectual property rights of others;*

*the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;*

*our plans to file additional patent applications to enhance and protect our existing intellectual property portfolio;*

*our ability to invalidate some or all of the claims covered by patents issued to competitors;*

*our estimates regarding our future revenues, research and development expenses, other expenses, payments to third parties and changes in staffing levels;*

*our estimates regarding how long our currently available cash and cash equivalents will be sufficient to finance our operations and statements about our future capital needs;*

*our expectations about funding from the government and other sources; and*

*other factors set forth below under the heading Risk Factors .*

*All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A Risk Factors of this Annual Report on Form 10-K.*

**Overview**

We are a biopharmaceutical company focused on the discovery and development of unique RNA-based therapeutics for the treatment of rare and infectious diseases. Applying our proprietary, highly-differentiated and innovative platform technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. We are primarily focused on rapidly advancing the development of our potentially disease-modifying Duchenne muscular dystrophy drug candidates, including our lead product candidate, eteplirsen. We are also focused on developing therapeutics for the treatment of infectious diseases, including our lead infectious disease program aimed at the development of a drug candidate for the Marburg hemorrhagic fever virus. By building our infectious disease programs which are primarily funded and supported by the U.S. government, and leveraging our highly-differentiated, proprietary technology platforms, we are seeking to further develop our research and development competencies and identify additional product candidates.

Our highly-differentiated RNA-based technologies work at the most fundamental level of biology and potentially could have a meaningful impact across a broad range of human diseases and disorders. Our lead program focuses on the development of disease-modifying therapeutic candidates for Duchenne muscular dystrophy, or DMD, a rare genetic muscle-wasting disease caused by the absence of dystrophin, a protein necessary for muscle function. Currently, there are no approved disease-modifying therapies for DMD. Eteplirsen is our lead therapeutic candidate for DMD. If we are successful in our development efforts, eteplirsen will address a severe unmet medical need. Last year, we completed a U.S.- based Phase IIb clinical trial for eteplirsen that was initiated in August 2011. Following completion of this study in early 2012, we initiated an open label extension study that is expected to be completed in late 2013 with the same participants from the original Phase IIb placebo controlled trial. We anticipate initiating a pivotal clinical trial for eteplirsen by the end of 2013 and commencing dosing in this trial early 2014.

We are also leveraging the capabilities of our RNA-based technology platforms to develop therapeutics for the treatment of infectious diseases. The U.S. Department of Defense, or DoD, has provided significant financial

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support in the past for the development of therapeutics against Ebola, Marburg, Dengue and influenza viruses. We have attracted DoD s support based in part on our ability to rapidly respond to pathogenic threats by quickly identifying, manufacturing and evaluating novel therapeutic candidates as discussed in greater detail in the section captioned Development Programs Infectious Disease Programs Influenza Program below.

The basis for our novel RNA-based therapeutics is our phosphorodiamidate-linked morpholino oligomer, or PMO, chemistries. Unlike other RNA-based therapeutics, which are often used to down-regulate gene expression, our technologies can be used to selectively up-regulate or down-regulate the production of a target protein, or direct the expression of novel proteins involved in human diseases and disorders. Further, we believe the charge-neutral nature of our PMO-based molecules may have the potential to reduce off-target effects, such as immune stimulatory effects often seen in alternative RNA-based technologies. We believe that our highly-differentiated, novel proprietary and innovative RNA-based technology platforms, based on charge neutral morpholino oligomers, may represent a significant improvement over traditional RNA-based technologies.

We were incorporated in the State of Oregon on July 22, 1980. Our executive office is located at 215 First Street, Suite 7 Cambridge, MA 02142 and our telephone number is (857) 242-3700. Our common stock trades on The NASDAQ Global Market under the symbol SRPT. On July 12, 2012, our common stock began trading on The NASDAQ Global Market on a split-adjusted basis following a one-for-six reverse stock split that was effective on July 11, 2012. Unless otherwise noted, all share amounts, share prices and exercise prices included throughout this report give effect to the July 2012 one-for-six reverse stock split.

This Annual Report on Form 10-K includes our trademarks and registered trademarks, including PMO*plus*®, PMO-X, AVI BioPharma®, Sarepta, Sarepta Therapeutics, Cytoporter® and NeuGene®. Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

**Where You Can Find Additional Information**

We make available free of charge through our corporate website, www.sareptatherapeutics.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, Sarepta Therapeutics, Inc., 215 First Street, Suite 7, Cambridge, MA 02142, e-mail: investorrelations@sareptatherapeutics.com. Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the Securities and Exchange Commission, or the SEC, at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

**Objectives and Business Strategy**

We believe that our highly-differentiated, proprietary RNA-based technology platforms can be used to develop novel pharmaceutical products to treat a broad range of diseases and address key unmet medical needs. We intend to leverage our RNA-based technology platforms, organizational capabilities and resources to become a leading developer and marketer of RNA-based therapeutics, including for the treatment of rare and infectious diseases, with a diversified portfolio of product candidates and approved products. In pursuit of this objective, we intend to engage in the following activities:

- advancing the development of eteplirsen and our other drug candidates for the treatment of DMD to realize the product opportunities of such candidates and provide significant clinical benefits;

- successfully executing our government funded infectious disease therapeutic programs and building on and leveraging our experience with such programs to further develop our research and development capabilities and garner additional external funding; and

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leveraging our highly-differentiated, proprietary RNA-based technology platforms to identify product candidates in additional therapeutic areas and explore various strategic opportunities, including potential partnering, licensing or collaboration arrangements with industry partners.

**Development Programs**

Our currently active RNA-based drug programs are being clinically evaluated for the treatment of DMD and have also demonstrated promising antiviral activity in infectious diseases such as Marburg and H1N1 influenza in certain animal models. Our active lead product candidates are at various stages of development summarized below.

| Program | Indication | Mechanism | Chemistry | Development Stage | Developer / Collaborator |
|---|---|---|---|---|---|
| Eteplirsen | DMD (exon 51) | Exon Skipping | PMO | Phase IIb* | Proprietary |
| AVI-7288 | Marburg virus | Translation Suppression | PMO*plus*® | Phase I | Proprietary/U.S. Government |
| AVI-7100 | H1N1 influenza virus | Translation Suppression | PMO*plus*® | Phase I | Proprietary/U.S. Government |

* We announced results from our Phase IIb clinical study in eteplirsen in April 2012 and are currently conducting an open label extension phase to this clinical trial.

For purposes of the table, Development Stage indicates the most advanced stage of development that has been completed or is ongoing. In the table above, under the heading Development Stage, Phase IIb indicates clinical safety and efficacy testing in a small patient population, and Phase I indicates initial clinical safety testing in healthy volunteers or a limited patient population, or trials directed toward understanding the mechanisms or metabolism of the drug.

***Duchenne Muscular Dystrophy Program***

Duchenne muscular dystrophy, or DMD, is one of the most common fatal genetic disorders affecting children (primarily boys) around the world. DMD is a devastating and incurable muscle-wasting disease associated with specific mutations in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. The absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. The disease occurs in approximately one in every 3,500 male births worldwide. Females are rarely affected by the disorder. Initial symptoms, which usually appear between the ages of three and five, include progressive muscle weakness of the legs and pelvis, manifested as difficulty walking, running or climbing stairs, which eventually spreads to the arms, neck, and other areas. By age ten, braces may be required for walking, and many individuals require full-time use of a wheelchair before age 12. Eventually muscular degeneration progresses to the point of complete paralysis. Disease progression is also typically associated with respiratory muscle dysfunction and a corresponding difficulty in breathing, which may require ventilatory support, and cardiac muscle dysfunction which may lead to heart failure. DMD is ultimately fatal and death usually occurs before the age of 30. There is currently no approved disease modifying treatment or cure for DMD.

The yearly cost of care for individuals with DMD is high and increases with disease progression. Although DMD is a rare disease, it represents a substantial product opportunity due to the severity and inexorable progression of the symptoms.

Our lead program is designed to address specific gene mutations that result in DMD by forcing the genetic machinery to skip over an adjacent contiguous piece (*i.e.*, one or more exons) of RNA and, thus, restore the ability of the cell to express a new, truncated but functional, dystrophin protein. We believe that the expression of

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this truncated dystrophin protein may restore, prevent or slow deterioration of muscle function, as exemplified by the less severe muscular dystrophy phenotype, called Becker muscular dystrophy.

*Eteplirsen*. Eteplirsen is an antisense PMO-based therapeutic in clinical development for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that can be treated by skipping exon 51. Eteplirsen targets the most frequent series of mutations that cause DMD. Eteplirsen has been granted orphan drug designation in the United States and European Union. In 2007, the FDA granted eteplirsen fast track status and we are currently evaluating the possibility of seeking certain types of expedited review or approval for eteplirsen. See Government Regulation for additional information.

In October 2010, we announced results from a clinical trial of eteplirsen, AVI Study 28. Data from this study were published in *The Lancet* in July 2011. AVI Study 28 was a Phase Ib/IIa open label, dose-ranging, clinical trial assessing the safety, tolerability, pharmacokinetics and exploratory efficacy of eteplirsen in ambulatory individuals with DMD. Participants in AVI Study 28 were between the ages of five and 15 with errors in the gene coding for dystrophin, which were amenable to treatment by skipping exon 51. Participants were dosed once per week for 12 weeks. A total of 19 participants were enrolled and these individuals were assigned to one of six dose cohorts of 0.5, 1.0, 2.0, 4.0, 10.0 or 20.0 mg/kg. Of the 19 participants enrolled, 18 received at least ten of the 12 doses planned in this trial. After completion of dosing, participants were followed for an additional 14 weeks. Muscle biopsies were taken before treatment and 17 participants had a second biopsy at week 14, two weeks after administration of the final dose. The primary objective of the trial was to assess the safety of eteplirsen at these doses over the 26-week duration of the trial. Secondary trial objectives included assessment of plasma pharmacokinetics, urinary elimination and exploratory endpoints evaluating biological activity and clinical performance. This trial was conducted by investigators in the United Kingdom at the University College London Institute of Child Health / Great Ormond Street Hospital in London and at the Royal Victoria Infirmary in Newcastle-Upon-Tyne. In AVI Study 28, (i) eteplirsen induced exon 51 skipping in all cohorts and new dystrophin protein expression in cohort 3; (ii) eteplirsen was well-tolerated in all participants with no drug-related serious adverse events or severe adverse events, except that one participant exhibited deteriorating cardiac function, which was considered probably disease related; (iii) adverse events were mostly mild or moderate in intensity, not dose-related, and none were considered probably or definitely related to eteplirsen; and (iv) there was no detectable immune response to newly made dystrophin.

Based on the AVI 28 study results, we initiated a Phase IIb trial for eteplirsen in August 2011, AVI 4658-us-201, or Study 201, at Nationwide Children s Hospital in Columbus, Ohio and we announced the results from this study in April 2012. This was a randomized, double-blind, placebo-controlled study to assess the efficacy, safety, tolerability and pharmacokinetics of eteplirsen administered intravenously in two different doses over 24 weeks for the treatment of ambulant boys with DMD. Exploratory clinical measures of ambulation, muscle function and strength were also captured and evaluated during the course of the trial. Study 201 included 12 participants and muscle biopsies of all participants were performed prior to initiation of treatment. The 12 participants with a genotypically-confirmed appropriate genetic mutation were randomized into one of three treatment groups with four participants in each group. The first treatment group received a weekly intravenous administration of eteplirsen at a dose of 50.0 mg/kg. The second treatment group received a weekly intravenous administration of eteplirsen at a dose of 30.0 mg/kg. The third and final treatment group received a weekly administration of placebo. Participants receiving the 50.0 mg/kg dose received a second biopsy at 12 weeks after initiation of treatment, and participants receiving the 30.0 mg/kg dose received a second biopsy at 24 weeks after initiation of treatment. The results from Study 201 determined that treatment with eteplirsen met the primary efficacy endpoint in the study. Eteplirsen administered once weekly at 30mg/kg over 24 weeks resulted in a statistically significant ($p \leq 0.002$) increase in novel dystrophin (22.5% dystrophin-positive fibers as a percentage of normal) compared to no increase in the placebo group. In the study, a shorter duration of eteplirsen treatment, 12 weeks, did not show a significant increase in novel dystrophin (0.79% dystrophin-positive fibers as a percentage of normal; p-value NS), despite administration of the drug at a higher dose (50mg/kg once weekly). No significant improvements in clinical outcomes in the treated groups were observed compared to placebo.

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All participants in Study 201 were enrolled in an open-label extension study 4658-us-202, or Study 202, following the completion of Study 201 and all participants, including those from the placebo group in Study 201, are receiving either 30.0 mg/kg or 50.0 mg/kg for the duration of Study 202. The purpose of Study 202 is to evaluate the ongoing safety, efficacy and tolerability of eteplirsen. The primary efficacy endpoint was the change from baseline at week 48 in the percentage of dystrophin-positive fibers in muscle biopsy tissue as measured by immunohistochemistry. The primary clinical outcome measure was the change from baseline to week 48 on the six minute walk test, or the 6MWT. Study 202 is now in a long-term extension phase in which patients continue to be followed for safety and clinical outcomes approximately every 12 weeks through week 108 (which includes the original 28 weeks of Study 201).

On July 24, 2012, we announced interim results from Study 202 which indicated that treatment with eteplirsen over 36 weeks achieved a significant clinical benefit on the primary clinical outcome measure, the 6MWT, over a placebo/delayed treatment cohort. Eteplirsen administered once weekly at 50mg/kg over 36 weeks resulted in a 69.4 meter benefit compared to patients who received placebo for 24 weeks followed by 12 weeks of treatment with eteplirsen. In the predefined prospective analysis of the study s intent-to-treat population on the primary clinical outcome measure, the change in 6MWT distance from baseline, eteplirsen-treated patients who received 50mg/kg of the drug weekly demonstrated a decline of 8.7 meters in distance walked from baseline (mean=396.0 meters), while patients who received placebo/delayed-eteplirsen treatment for 36 weeks showed a decline of 78.0 meters from baseline (mean=394.5 meters), for a statistically significant treatment benefit of 69.4 meters over 36 weeks ($p \leq 0.019$). There was no statistically significant difference in the 6MWT between the cohort of patients who received 30mg/kg weekly of eteplirsen and the placebo/delayed treatment cohort. The safety profile of eteplirsen was evaluated across all subjects through the 36 weeks eteplirsen was administered and there were no treatment-related adverse events, no serious adverse events and no discontinuations. Furthermore, no treatment-related changes were detected on any safety laboratory parameters, including several biomarkers for renal function.

On October 3, 2012, we announced 48-week results from Study 202 which indicated that treatment with eteplirsen met the predefined primary efficacy endpoint, increase in novel dystrophin, and achieved a significant clinical benefit on the predefined primary clinical outcome measure, the 6MWT, over the placebo/delayed treatment cohort. Eteplirsen administered once weekly at either 30 mg/kg or 50 mg/kg for 48 weeks (n=8) resulted in a statistically significant increase ($p<0.001$) in dystrophin-positive fibers to 47.0% of normal. The placebo/delayed treatment cohort, which had received 24 weeks of eteplirsen at either 30 mg/kg or 50 mg/kg following 24 weeks of placebo (n=4), also showed a statistically significant increase in dystrophin-positive fibers to 38.3% of normal ($p<0.009$).

In the predefined prospective analysis of the study s intent-to-treat population on the primary clinical outcome measure, the change in 6MWT distance from baseline at week 48, eteplirsen-treated patients who received 50 mg/kg of the drug weekly (n=4) demonstrated an increase of 21.0 meters in distance walked from baseline (mean=396.0 meters), while patients who received placebo/delayed-eteplirsen treatment (n=4) showed a decline of 68.4 meters from baseline (mean=394.5 meters), for a statistically significant treatment benefit of 89.4 meters over 48 weeks ($p=0.016$, using analysis of covariance for ranked data). There was no statistically significant difference between the cohort of patients who received 30 mg/kg weekly of eteplirsen and the placebo/delayed treatment cohort. The safety profile of eteplirsen was evaluated across all subjects through 48 weeks and there were no treatment-related adverse events, no serious adverse events, and no discontinuations. Furthermore, no clinically significant treatment-related changes were detected on any safety laboratory parameters, including several biomarkers for renal function.

On December 7, 2012, we announced updated data from Study 202 which showed patients treated with eteplirsen for 62 weeks and evaluable on ambulatory measures (modified Intent-to-Treat population) maintained a statistically significant clinical benefit on the primary clinical outcome measure, the 6MWT, compared to patients who received placebo for 24 weeks followed by 38 weeks of eteplirsen treatment. In the mITT population, which includes evaluable patients from both the 30mg/kg and 50mg/kg dose cohorts, patients treated with eteplirsen for 62 weeks demonstrated a statistically significant benefit ($p \leq 0.007$) of 62 meters over the

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placebo/delayed-treatment cohort using a mixed-model repeated measure statistical test. The mITT population utilized for the 62 week analysis consisted of 10 of the enrolled 12 patients (4 eteplirsen-treated patients receiving 50 mg/kg weekly, 2 eteplirsen-treated patients receiving 30 mg/kg weekly, and 4 placebo/delayed-treatment patients), and excluded two patients who showed signs of rapid disease progression and lost ambulation by week 24. The eteplirsen treatment cohort (n=6) continued to show disease stabilization with less than a 5% decline in walking distance on the 6MWT from baseline. The placebo/delayed-treatment cohort (n=4) also demonstrated stability in walking distance from week 36 through week 62 with a less than 10 meter change over this timeframe, the period in which dystrophin was likely produced, with confirmation of significant dystrophin levels at week 48 through analysis of muscle biopsies in these patients.

The safety profile of eteplirsen was evaluated across all patients through week 62 and there were no clinically significant treatment-related adverse events, no serious adverse events, and no discontinuations. One patient had a laboratory treatment-related adverse event, a transient elevation of urine protein on a urine dipstick test, however this elevation was not observed on a 24-hour urine protein measurement and resulted in no clinical symptoms or interruption of treatment. This patient did not show elevations of the specific renal markers of cystatin C or KIM-1. Across both the treatment and placebo/delayed treatment cohorts there is evidence of continued stabilization on pulmonary function tests, echocardiogram, muscle strength and clinical laboratory tests over the 62 weeks.

Results from the mITT population, which combines the evaluable eteplirsen-treated patients across the 30mg/kg and 50mg/kg cohorts, have been previously reported and will be used as the primary assessment of ambulatory clinical measures for the remainder of Study 202. Given there was no significant difference between the 30 mg/kg and 50 mg/kg arms on the production of dystrophin through 48 weeks, this mITT population is the most appropriate to assess dystrophin production and its potential predictive benefits on ambulatory clinical outcomes, such as the 6MWT.

We are participating in an end of Phase II meeting with the FDA in the first quarter of 2013 to discuss the clinical results from our Phase IIb study of eteplirsen. Based on feedback from the meeting, we will make an initial determination regarding the most appropriate regulatory path for pursuing regulatory review and approval of eteplirsen. Any such initial determination will be further informed by a subsequent Chemistry, Manufacturing and Controls, or CMC, meeting with the agency. Regardless of the registration path ultimately pursued, we anticipate initiating a pivotal clinical trial by the end of 2013 and commencing dosing in early 2014.

*Pan-Exon Strategy*. In addition to our lead product candidate, eteplirsen, we are pursuing development of additional exon-skipping drugs, to support our broad-based development program for the treatment of DMD.

To support certain IND-enabling activities for an exon 45-skipping therapeutic, we are collaborating with Children s National Medical Center in Washington, D.C. and the Carolinas Medical Center. This collaboration will be funded primarily through two grants, one from DoD s Congressionally Directed Medical Research Program to Children s National Medical Center and the other from the National Institute of Neurological Disorders and Stroke to the Carolinas Medical Center. This funding is intended to pursue the most promising treatments for DMD. The collaboration will support a series of Good Laboratory Practice, or GLP, toxicology studies for an exon 45-skipping drug candidate based on our PMO chemistry.

To support certain clinical proof of concept studies and IND-enabling activities for an exon 53-skipping therapeutic, we announced in November 2012 that we are collaborating with University College London s scientist, Professor Francesco Muntoni, M.D., the Dubowitz Neuromuscular Centre, the Institute of Child Health and other scientists from the European Union and the United States. In connection with this collaboration, the consortium received an E.U. Health Innovation-1 2012 Collaborative research grant to support development of an exon 53-skipping therapeutic, based on our PMO chemistry. Targeting exon 53 with this technology will potentially address one of the most prevalent sets of mutations in DMD that are amenable to exon-skipping (deletion of exons 42-52, 45-52, 47-52, 48-52, 49-52, 50-52, or 52) by potentially restoring the cellular machinery s ability to produce a functional dystrophin protein.

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To support certain IND-enabling activities for an exon 50-skipping therapeutic, we entered into a Cooperative Research and Development Agreement, or CRADA, in August 2012 with the National Institutes of Health, or NIH, which was anticipated to be supported through in-kind research conducted either by the Therapeutics for Rare and Neglected Diseases program or by contract research organizations. We and NIH mutually agreed to terminate the CRADA in February 2013 and we are now developing exon 50 utilizing our own research and development capabilities. We do not anticipate any significant changes in IND filing timelines due to the termination.

These collaborations and our DMD program, which includes eteplirsen, are part of our larger pan-exon strategy for the development of drug candidates to address the most prevalent exon deletions in the DMD population. Because the majority of DMD patients have exon deletions that cluster together, a small number of exon-skipping therapies will potentially be disease-modifying for a relatively large percentage of DMD patients. Approximately 83% of the total DMD population is potentially treatable with exon-skipping therapeutics. Of this 83%, exon 51 skipping is applicable to the largest sub-group, equal to approximately 16%, and skipping of exons 50 and 45 is applicable to approximately 5% and 10%, respectively.

***Infectious Disease Programs***

With the financial support of the U.S. government, we are currently implementing our RNA-based technology platforms in our infectious disease programs for the development of therapeutics to treat infectious diseases, such as Marburg and influenza. DoD has provided significant financial support for our development of therapeutics designed to treat Ebola, Marburg, and influenza viruses and we recently entered into an agreement with the National Institute of Allergy and Infectious Diseases, or NIAID, part of NIH, under which NIAID will provide clinical support for the development of a therapeutic designed to treat influenza.

Our current arrangement with DoD supporting the development of our Marburg drug candidate provides funding for all clinical and licensure activities necessary to obtain approval of a New Drug Application, or a NDA, by the FDA if DoD exercises all of its options under the arrangement. On August 29, 2012, we entered into an additional agreement with DoD related to the Marburg virus to evaluate the feasibility of an intramuscular route of administration using AVI-7288. Under a separate arrangement, DoD similarly provided funding to advance the development of our H1N1 influenza drug candidate through an IND, application with the FDA and to preclinically evaluate its therapeutic potential against H5N1 (avian flu), Tamiflu® resistant H1N1 (pandemic flu) and H3N2 (seasonal flu) which concluded in 2011. In December 2012, we entered into an agreement with NIAID to support the further development of a drug candidate against influenza viruses AVI-7100. Under the agreement, NIAID researchers are allowed to proceed with a Phase I, study to assess the safety, tolerability and pharmacokinetics of single and multiple doses of AVI-7100 in healthy volunteers. Per the terms of the agreement, we will provide AVI-7100 to NIAID and in return, we will have the right to use the data from this clinical study to support future development of AVI-7100.

Without continued government support of these programs we would likely significantly curtail our development efforts. Future funding and support is subject to availability of budgeted funds from DoD and the Department of Health and Human Services, or DHHS, as government support for some of our infectious disease programs has previously been discontinued or not renewed due to government budget constraints. For example, our current arrangement with DoD initially provided for support of the development of our Ebola virus drug candidate; however, on October 2, 2012, the Company received notice from DoD that the Ebola portion of the arrangement was terminated for the convenience of the government due to funding constraints. The Company previously received a stop-work order for the Ebola portion of the arrangement with DoD which was in effect from August 2, 2012 through the termination on October 2, 2012. The termination only applies to the Ebola portion of the arrangement with DoD and the Marburg portion remains actively in development under the DoD arrangement. Additionally, the period of performance for our June 2010 H1N1 influenza contract with DoD expired in June 2011 and our subsequent submissions to a DoD request for proposal, or RFP, for funding of the full clinical development of our influenza drug candidate, AVI-7100, were unsuccessful, although additional research for this antiviral program is being conducted by NIAID as described elsewhere in this report.

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In the periods presented in this report, substantially all of our revenues were derived from research and development contracts with and grants from the U.S. government. As of December 31, 2012, we had completed all of our contracts with the U.S. government except for the Marburg portion of the July 2010 agreement for the development of therapeutics against Marburg and Ebola viruses and the August 2012 agreement for the intramuscular administration of our product candidate against the Marburg virus. Pursuant to these agreements, as of December 31, 2012, the remaining funding for the current segments of the contracts is approximately $19.8 million. In addition, if the U.S. government elects to exercise all its options under the agreements, an additional $84.4 million in funding is available. For a more detailed description of our contracts with the U.S. government, see Management s Discussion and Analysis of Financial Condition and Results of Operations U.S. Government Contracts and Note 6 U.S. Government Contracts of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

*Hemorrhagic Fever Virus Programs*. Our infectious disease therapeutic programs use our translation suppression technology and apply our proprietary PMO*plus*® chemistry backbone, an advanced generation of our base PMO chemistry backbone that selectively introduces positive backbone charges to improve selective interaction between the drug and its target. Our translation suppressing technology is based on Translation Suppressing Oligomers, or TSOs, which are PMO-based compounds that stop or suppress the translation of a specific protein by binding to their specific target sequence in mRNA. We are pursuing development and regulatory approval of our Marburg hemorrhagic fever virus product candidates under the FDA s Animal Rule. The Animal Rule provides that under certain circumstances, where it is unethical or not feasible to conduct human efficacy studies, the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans. Demonstration of the product s safety in humans is still required. See Government Regulation Animal Rule for additional information.

Marburg virus. AVI-7288 is designed for post-exposure prophylaxis after documented or suspected exposure to Marburg virus. Marburg hemorrhagic fever is a severe and often fatal disease in humans that was first recognized in 1967. It is caused by an RNA virus of the Filoviridae family and is understood to be endemic to Africa. The Marburg virus is classified as a Category A bioterrorism agent by the Centers for Disease Control and Prevention, or CDC, and was determined to be a material threat to national security by the Secretary of Homeland Security in 2006. Onset of the disease is often sudden and the symptoms include fever, chills, nausea, vomiting, chest pain and diarrhea. Increasingly severe symptoms may also include massive hemorrhaging and multiple organ dysfunction. There are currently no treatments for Marburg virus infection beyond supportive care and the mortality rate is very high. For Marburg virus infection, our lead product candidate is currently AVI-7288. Previously, our lead product candidate for Marburg virus infection was AVI-6003 which is a combination of AVI-7287 and AVI-7288; however, in February 2012, we announced that we received agreement from the FDA to remove AVI-7287 and we are now proceeding with a single oligomer approach, AVI-7288, given that efficacy in non-human primates has been demonstrated to be attributable to this single oligomer. During the 2012 fiscal year, we completed Phase I single ascending-dose studies in healthy volunteers with our candidates for the treatment of Ebola virus and Marburg virus and in July 2012, we announced results from a non-human primate study of the efficacy of AVI-7288. With the support of DoD s Joint Project Manager Transformational Medical Technologies we are also evaluating the feasibility of in intramuscular route of administration using AVI-7288, including an evaluation of the tolerability, pharmacokinetics, and efficacy of intramuscular AVI-7288. In September 2012, we announced that the FDA has granted fast track status for the development of AVI-7288 and our product candidate against Ebola, AVI-7537.

Ebola virus. AVI-7537 is a single agent designed for post-exposure prophylaxis after documented or suspected exposure to the Ebola virus. The hemorrhagic fever caused by the Ebola virus is severe and often fatal in humans and there are currently no treatments for Ebola beyond supportive care. AVI-6002, a combination of AVI-7537 and AVI-7539, was previously our product candidate for the Ebola virus. However, based on our evaluation of the efficacy of AVI-7537 as a single agent versus a combination with AVI-7539 which demonstrated that efficacy could be attributed to the single oligemer AVI-7537, we transitioned our focus to this

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product candidate in 2012. Although we believe AVI-7537 has the potential to be a therapeutic option for the Ebola virus, we suspended our development efforts with respect to our Ebola program after the August 2012 stop-work order and subsequent termination by DoD of support for this program in 2012. The termination only applies to the Ebola portion of our arrangement with DoD and the Marburg portion remains in effect.

Development Status of Hemorrhagic Fever Virus Programs. Non-human primates infected with Marburg virus and treated with our precursor product candidate, AVI-6003, achieved 100% survival and primates infected with Ebola virus and treated with, AVI-6002, achieved 80% survival, in each case compared to universal lethality in both control groups. In addition to survival, primates treated with AVI-6002 and AVI-6003 have demonstrated decreases in levels of viremia, in harmful inflammatory indicators and in virus induced liver damage. Additional data have also demonstrated that the surviving animals were resistant to viral infection after subsequent injection with the virus.

During the 2012 fiscal year, Sarepta completed Phase I single ascending-dose studies in healthy adult volunteers with its drug candidates for the treatment of Ebola virus and Marburg virus demonstrating positive safety data for each therapeutic candidate. In February 2012, we announced positive safety results from all six cohorts of our Phase I single ascending dose trials of AVI-6002 and AVI-6003. For each group, safety, clinical laboratory and renal biomarker results through five days after treatment were reviewed by an independent Data and Safety Monitoring Board, or DSMB, which issued recommendations for both studies to progress as planned to multiple ascending dose studies after no safety concerns were identified. The Phase I single ascending dose trials were designed to characterize the safety, tolerability and pharmacokinetics of each therapeutic candidate in healthy adult volunteers. In the two studies, a total of 60 healthy human subjects (five per group) were enrolled into six sequential dose groups (0.01, 0.1, 1.0, 3.0, 6.0 or 9.0 mg/kg). Within each group, four subjects received the indicated dose of the therapeutic and one subject received placebo. Final, unblinded safety and pharmacokinetic results for all subjects were completed in 2012.

In July 2012, we announced that AVI-7288 demonstrated up to 100% survival in a non-human primate study exploring the drug s effect when the initiation of treatment is delayed to various time points post-infection. This study showed a high degree of survival between 83% and 100% in each of four post-exposure cohorts that received daily treatments with AVI-7288 beginning one-, 24-, 48-, or 96-hours after infection, compared to 0% survival in the placebo-treated control group.

We plan to initiate a Phase I multiple ascending dose study in the first half of 2013, which is designed to characterize the safety, tolerability and pharmacokinetics of multiple doses of AVI-7288 in healthy adult volunteers. The randomized, double-blind placebo controlled studies will be overseen by an independent DSMB, which will review safety and clinical laboratory data after each dose cohort prior to enrolling the next higher dose cohort.

*Influenza Program.* Our infectious disease therapeutic programs are also focused on the development of our product candidates designed to treat pandemic influenza viruses. AVI-7100 is our lead product candidate for the treatment of influenza and employs our PMO*plus*® technology. In December 2012, we entered into a contract with NIAID which permits NIAID to conduct a Phase I single and multiple ascending dose study with AVI-7100. In June 2010, we were awarded a contract under DoD s Transformational Medical Technologies, or TMT, program, which funded our activities to develop AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus. The period of performance for this contract ended in June 2011. See Management s Discussion and Analysis of Financial Condition and Results of Operations U.S. Government Contracts and Note 6 U.S. Government Contracts of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Symptoms of H1N1 influenza include fever, cough, runny nose, headache, chills and fatigue. Many people infected with H1N1 also have respiratory symptoms without a fever. Severe illness and deaths have also occurred. The CDC estimated that between April 2009 and April 2010 there were up to 89 million cases of H1N1 infection in the United States. The CDC also estimated that there were up to 403,000 H1N1-related hospitalizations in the United States during the same time period.

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The TMT program established a contract with us to conduct a rapid response exercise against a real-world emerging threat like the pandemic H1N1 virus. The intent of the exercise was to demonstrate our capability to efficiently respond to a real-world emerging viral threat by rapidly designing and producing multiple therapeutic candidates and evaluating preclinical efficacy. Initially the exercise involved identifying target sequences against H1N1, designing several drug candidates utilizing proprietary derivatives of our PMO chemistry, and then manufacturing the candidates in sufficient quantity for limited preclinical testing. We successfully accomplished these steps in approximately one week, demonstrating our ability to rapidly respond to a real-world viral threat utilizing our RNA-based technology platforms.

Subsequently, we evaluated the preclinical activity of AVI-7100 and found that it showed a favorable safety profile in ferrets, rats and monkeys. In separate ferret studies, AVI-7100 demonstrated activity as a potentiator of Tamiflu and activity towards preventing transmission of Tamiflu-resistant H1N1.

In June 2011, we initiated dosing of AVI-7100 via intravenous infusion in single-ascending doses in up to 48 healthy adult volunteers. The first dose cohort in this Phase I, randomized, double-blind, placebo-controlled study was completed and received a favorable review from the DSMB to proceed to the next dose escalation. The period of performance under this DoD contract subsequently ended and, as a result, continued development was suspended until we entered into the clinical trial agreement with NIAID.

Under the December 2012 agreement with NIAID, NIAID researchers are allowed to proceed with a Phase I, double-blind, placebo-controlled, dose-escalating study to assess the safety, tolerability and pharmacokinetics of single and multiple doses of an intravenous formulation of AVI-7100 in healthy volunteers. Per the terms of the agreement, we will provide AVI-7100 to NIAID and in return, we will have the right to use the data from this clinical study to support future development of AVI-7100.

**Discovery Stage Program Overview**

Our PMO-chemistries are highly-differentiated from other RNA technologies, including antisense, siRNA and RNAi. Unlike these technologies, which are often used for down-regulation of gene expression, ours can be used to selectively up-regulate or down-regulate the expression of proteins involved in human diseases and disorders, or direct the production of novel proteins with clinically relevant properties.

In addition to our pan-exon strategy for DMD, our preclinical research efforts are focused on the creation of product candidates for the treatment of other neuromuscular, infectious and rare diseases.

**Chemistry Technology**

Our core chemistry is based on phosphorodiamidate-linked morpholino oligomers, or PMOs, and this core chemistry has been safely dosed in over 400 patients PMOs are synthetic molecules based on a fundamental redesign of the natural nucleic acid structure of DNA and RNA. PMOs bind to complementary sequences of RNA by standard Watson-Crick nucleic acid base-pairing and control gene expression by steric blockade of targeted RNA. Structurally, the key difference between PMOs and naturally occurring DNA and RNA is that while PMOs, like DNA and RNA, have nucleic acid bases, those bases are bound to synthetic morpholine rings instead of deoxyribose (in DNA) or ribose (in RNA) rings, and they are linked through phosphorodiamidate groups instead of phosphate groups. Replacement of anionic phosphates with the charge-neutral phosphorodiamidate groups eliminates ionization in the usual physiological pH range, thus PMOs in organisms or cells are uncharged molecules. Because of these modifications, PMOs are especially resistant to degradation by plasma and intracellular enzymes. Unlike some other RNA-based technologies, including siRNAs and other types of antisense, PMOs rely on steric blocking rather than cellular enzymatic activity for their biological effects. In this way, PMOs operate fundamentally differently from other well-known RNA-based technologies.

We have developed three new PMO-based chemistry platforms in addition to our original PMO-based technology. We believe that the novel, favorable characteristics intrinsic in these new platforms will allow for the development of drug candidates with superior delivery specificity, therapeutic windows and drug-like properties.

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*PPMO*. The first of these novel chemistries is based on peptide conjugated PMOs, or PPMOs, in which cellular uptake of the PMO component, as well as its potency and specificity of tissue targeting, may be significantly enhanced.

*PMOplus*®. The second of these chemistries, PMO*plus*®, includes the addition of selectively introduced positive charges to the PMO backbone. We believe that while PMO*plus*® has potentially broad therapeutic applications, it has thus far shown to be particularly effective in increasing the potency of PMO-based oligomers.

*PMO-X*. The third of these chemistries, PMO-X, involves novel, selective, and proprietary backbone chemistry modifications. We believe PMO-X may provide enhanced in vivo potency for our drug candidates, as well as greater flexibility in modulation of their tissue targeting, cellular delivery and uptake.

We intend to continue to support our internal research and development efforts in order to advance our proprietary chemistries and to develop new analogues that may provide additional benefits in key characteristics of drug performance.

**Mechanisms of Action**

Humans have far fewer genes than the number of unique proteins expressed in the human proteome. The genetic information stored in human DNA is not contiguous. Short DNA stretches, called exons that code for fragments of the protein are separated by long non-coding pieces of DNA called introns. During processing of precursor or pre-mRNA, which is copied from the DNA template, introns are removed and exons spliced together to create the mature mRNA, from which a functional protein can be made. Pre-mRNA copied from a gene can be spliced through alternative paths, such that different exons are combined, creating multiple mRNAs and, hence, generate multiple proteins from a single gene.

Our PMO-based molecules are designed to sterically block the access of cellular machinery to pre-mRNA and mRNA without degrading the RNA. Through this selective targeting, two distinct biologic mechanisms of action can be initiated: (1) modulation of pre-mRNA splicing (also commonly described as splice switching, exon skipping or directed alternative splicing) and (2) inhibition of mRNA translation (also commonly described as translation suppression). Through these mechanisms, steric-blocking oligonucleotides can repair defective RNA, up or down-regulate the production of selected proteins, or produce novel or remodeled proteins.

**Material Agreements and Strategic Alliances**

We believe that our RNA-based technology could be broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To further exploit our core technology, we have and may continue to enter into research, development or commercialization alliances with universities, hospitals, independent research centers, non-profit organizations and pharmaceutical and biotechnology companies for specific molecular targets or selected disease indications. We may also selectively pursue opportunities to access certain intellectual property rights that complement our internal portfolio through license agreements or other arrangements.

***U.S. Department of Defense and DHHS Agreements***

We currently have contracts with DoD and its agencies and DHHS and its agencies, funding and supporting our programs. For a more detailed description of our contracts with the U.S. government, see Management s Discussion and Analysis of Financial Condition and Results of Operations U.S. Government Contracts below and Note 6 U.S. Government Contracts of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our contracts with the government may be subject to renegotiation or termination at the election of the government. For a description of the risks we face relating to such rights of the government see Risk Factors Risks Relating to Our Business

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***University of Western Australia***

In November 2008, we entered into an exclusive license with the University of Western Australia, or UWA, for certain patents and technical information relating to the use of certain antisense sequences for the treatment of DMD. The license grants us specific rights to the treatment of DMD by inducing the skipping of certain exons. Unless earlier terminated in accordance with the terms of the agreement, such agreement will expire on the expiration date of the last to expire patent within the patents licensed to us under the agreement. Our clinical candidate, eteplirsen, falls under the scope of this agreement. Any future drug candidates developed for the treatment of DMD by exon skipping may or may not fall under the scope of this agreement.

Under the agreement, we are required to meet certain performance diligence obligations related to development and commercialization of products developed under license. We believe we are currently in compliance with these obligations. We made an initial upfront payment to UWA on execution of the license. We may be required to make additional payments to UWA of up to a total of $150,000 based on successful achievement of certain regulatory-related milestones and also may be required to pay royalties ranging from a fraction of a percent to the low single digits on net sales of products covered by issued patents licensed from UWA during the term of the agreement. As of December 31, 2012, we have made milestone payments to UWA of approximately $10,000, but have not made, and are not under any current obligation to make, any royalty payments to UWA until a product candidate is approved for commercial sale.

**Strategic Alliances**

***Isis Ercole Agreement***

In May 2003, Ercole Biotechnology, Inc., or Ercole, and Isis Pharmaceuticals, or Isis, entered into a collaboration and license agreement related to RNA splicing. In March 2008, we acquired all of the stock of Ercole in exchange for 5,811,721 shares of our common stock, which was valued at approximately $8.4 million, and the assumption of approximately $1.8 million in liabilities of Ercole. We also issued warrants to purchase our common stock (also classified as equity), which were valued at $437,000, in exchange for certain outstanding warrants issued by Ercole. In connection with the March 2008 acquisition, we assumed Ercole s obligations under the Isis agreement. This agreement contains several cross-licenses between the parties granting each party certain exclusive and nonexclusive rights under a selected set of the other parties patents and patent applications for the research, development, and commercialization of antisense therapeutics using RNA splicing with respect to certain gene targets.

Subject to the satisfaction of certain milestones triggering the obligation to make any such payments, we may be obligated to make milestone payments to Isis of up to $23.4 million in the aggregate for each product developed under a licensed patent under this agreement.

As of December 31, 2012, we have not made, and are not under any current obligation to make, any such milestone payments, as the conditions triggering any such milestone payment obligations have not been satisfied. The range of percentage royalty payments required to be made by us under the terms of this agreement is from a fraction of a percent to mid single digits. We believe that our DMD, Ebola, Marburg and influenza programs will not fall under the scope of this agreement and therefore will not be subject to milestone or royalty obligations under its provisions.

Subject to the satisfaction of certain milestones triggering the obligation to make any such payments, Isis may be obligated to make milestone payments to us of up to $21.1 million in the aggregate for each product developed under a licensed patent under this agreement. As of December 31, 2012, Isis has not made any such milestone payments, as the conditions triggering any such milestone payment obligations have not been satisfied. The percentage royalty payments required to be made by Isis under the terms of this agreement is a fraction of a percent. As to any product commercialized under the agreement, the agreement will terminate on the expiration date of the last to expire licensed patent covering such product. Research collaboration activity defined in the agreement expired in 2006.

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***Charley s Fund Agreement***

In October 2007, Charley s Fund, Inc., or Charley s Fund, a nonprofit organization that funds drug development and discovery initiatives specific to DMD, awarded us a $2.45 million research grant and, in May 2009, the grant authorization was increased to a total of $5.0 million. Pursuant to the related sponsored research agreement, the grant was provided to support the development of product candidates related to exon 50 skipping using our proprietary exon skipping technologies. As of December 31, 2012, Charley s Fund has made payments of approximately $3.4 million to us. Revenue associated with this research and development arrangement is recognized based on the proportional performance method, using the payment received method. To date, we have recognized $60,000 as revenue, but did not recognize any revenue for the years ended December 31, 2012, 2011 and 2010. We do not expect to receive any incremental funding under the grant and have deferred $3.3 million of previous receipts which are anticipated to be recognized as revenue once we complete the remaining milestones.

Under the terms of the sponsored research agreement, as amended, if we and any of our strategic partners elect to discontinue the development and commercialization of any product containing any molecular candidate arising or derived from the research sponsored by Charley s Fund for reasons other than safety or efficacy, we must grant to Charley s Fund an exclusive, royalty-bearing, fully-paid, worldwide license, with right of sublicense, to any such product. Depending on whether and when Charley s Fund obtains a license to any such product, percentage royalty payments on net sales required to be made by Charley s Fund to us under the terms of the sponsored research agreement, as amended, would be in the mid single digits. Under the terms of the sponsored research agreement, as amended, if we are able to successfully commercialize any molecular candidate arising or derived from the research sponsored by Charley s Fund either through sales of products or through licensing or partnership arrangements with a third party that include rights for such third party to sell, distribute, promote or market such products or the underlying intellectual property, then we are obligated to repay the research funds paid to us by Charley s Fund, up to an amount equal to the total amount of funds provided by Charley s Fund to us. In connection with this repayment obligation, we agreed that we would pay a mid range single-digit percentage royalty on net sales of products containing any molecular candidate arising or derived from the research sponsored by Charley s Fund and a mid-teens amount of any upfront cash and/or milestone payments received from a licensing or partnership arrangement with a third party with respect to such products (in each case, up to an amount equal to the total amount of funds provided by Charley s Fund to us). This agreement will terminate by its own terms at the completion of the research being sponsored by Charley s Fund. The Sarepta technology upon which the agreement is based is covered by certain patents, the last of which expires following the termination of the agreement.

Previously, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038, our PMO-based candidate designed for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that can be treated by skipping exon 50. We have conducted additional preclinical studies and have not alleviated the toxicity problem. Pursuant to the terms of our agreement with Charley s Fund, the receipt of additional funds is tied to the satisfaction of certain clinical milestones. Because of the toxicity issues with AVI-5038, satisfaction of the additional milestones under the agreement is unlikely and we do not expect to receive any additional funds from Charley s Fund.

**Manufacturing**

We believe we have developed proprietary manufacturing techniques that allow synthesis and purification of our product candidates to support clinical development. We have entered into certain manufacturing and supply arrangements with third-party suppliers which will in part utilize these techniques to support production of certain of our product candidates and their components. We do not have, and do not intend to establish in the near term, any of our own internal mid-to-large scale manufacturing capabilities to support our product candidates.

For our current development programs we have entered into supply agreements with certain large pharmaceutical manufacturing firms for the production of the custom raw materials required for PMO production and the active pharmaceutical ingredients, or APIs, for our product candidates.

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For our DMD program, during the first half of this year, we are working to increase our API production capacity from small-scale to mid-scale with our existing manufacturers. During 2013, we will also evaluate whether to increase our API production capacity to a commercial scale. This decision will depend in significant part on our discussions with the FDA in 2013 as well as our expectations regarding if, and when, we would commence a pivotal trial for eteplirsen and potential commercialization.

There are a limited number of companies that can produce raw materials and APIs in the quantities and with the quality and purity that we require for our DMD development efforts. Due to their technical expertise, experience in manufacturing our product candidates and sophistication of their manufacturing facilities and quality systems, we are considering our existing manufacturers, as well as other manufacturers with relevant expertise, for the further scale-up of the production of raw materials and APIs for our DMD program. Establishing a relationship with alternative suppliers can be a lengthy process and might cause delays in our development efforts. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

Manufacturers and suppliers of product candidates are subject to the FDA s current Good Manufacturing Practices, or cGMP, requirements, and other rules and regulations prescribed by foreign regulatory authorities. We depend on our third-party suppliers and manufacturers for continued compliance with cGMP requirements and applicable foreign standards.

**Sales and Marketing Strategy**

We have not obtained regulatory approval for any of our product candidates and thus have not yet established a commercial organization or distribution capabilities. Due to the rare nature of DMD and the lack of disease-modifying treatments, patients suffering from DMD, together with their physicians, often have a high degree of organization and are well informed, which may simplify the identification of a target population for eteplirsen, our lead product candidate, if it is approved. We believe that, if approved for commercial sale, it will be possible to commercialize eteplirsen with a relatively small specialty sales force that calls on the physicians, foundations and other patient-advocacy groups focused on DMD. Our current expectation is to commercialize eteplirsen ourselves in the United States and plan to recruit a sales force and take other steps to establish the necessary commercial infrastructure at such time as we believe that eteplirsen is approaching marketing approval. We will continue to evaluate whether to market our DMD product candidates outside of the United States ourselves or enter into arrangements with other pharmaceutical or biotechnology companies for the marketing and sale of our products outside the United States either globally or on a country-by-country basis.

**Patents and Proprietary Rights**

Our success depends in part upon our ability to protect our core technology and intellectual property. To accomplish this, we rely on a combination of intellectual property rights, including patents, trade secrets, copyrights and trademarks, and contractual protections.

We seek appropriate patent protection for our proprietary technologies by filing patent applications in the United States and other countries. As of February 28, 2013, we owned or controlled approximately 290 U.S. and corresponding foreign patents and 185 U.S. and corresponding foreign patent applications. We intend to protect our proprietary technology with additional filings as appropriate.

Our patents and patent applications are directed to our product candidates as well as to our RNA-based technology platforms. Although we believe our patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our collaborators may not be able to develop patentable products or

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processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us or our collaborators. For example, our competitor Prosensa has rights to European Patent No. EP 1619249. We opposed this patent in the Opposition Division of the European Patent Office, or the Opposition Division, and in November 2011, we announced that, although we succeeded in invalidating some of the patent s claims, the Opposition Division maintained in amended form certain claims of this patent relating to the treatment of DMD by skipping dystrophin exons 51 and 46. We and Prosensa both have the right to appeal this decision; however, pending final resolution of this matter and any appeal thereof, the patent at issue may provide the basis for Prosensa or other parties that have rights to such patent to assert that our drug eteplirsen infringes on such patent. The timing and outcome of an appeal, if pursued, cannot be predicted or determined as of the date of this report. We are also aware of certain claims that have issued to Prosensa in Japan that may provide the basis for Prosensa or other parties that have rights to these claims to assert that our drug eteplirsen infringes on such claims. We believe we have a basis to invalidate some or all of these claims and are evaluating the potential initiation of invalidation proceedings. Because we have not yet initiated an invalidation proceeding in Japan, the outcome and timing of such proceeding cannot be predicted or determined as of the date of this report. If as part of any appeal in the European Union we are unsuccessful in invalidating other of Prosensa s claims or if previously invalidated claims are restored on appeal, our ability to commercialize both eteplirsen and other therapeutic candidates for our pan-exon strategy could be materially impaired. We are also aware of certain claims that Prosensa has rights to in the United States that may provide the basis for Prosensa or other parties that have rights to these claims to assert that our drug eteplirsen infringes on such claims. We believe we have valid defenses to any such allegations or a basis to invalidate some or all of these claims and do not believe that Prosensa s patent seriously harms our ability to develop and commercialize our products; however, we cannot be certain of this. The DMD patent landscape is continually evolving and multiple parties, both commercial entities and academic institutions, may have rights to claims that could provide these parties a basis to assert that our product candidates infringe on these claims. Similarly, we may be able to assert that certain activities engaged in by these parties infringe on our patent rights. There has been, and we believe that there will continue to be, significant litigation in the biopharmaceutical and pharmaceutical industries regarding patent and other intellectual property rights. We also cannot be certain that other third parties will not assert patent infringement in the future with respect to any of our development programs.

Our clinical product candidates and our technology are protected by composition and use patents and patent applications. Patent protection afforded by the patents and patent applications covering our product candidates and out technology will expire over the following time frames:

| Product Candidate / Technology | Expiration of Patent Protection |
|---|---|
| Eteplirsen | 2025 (patents) 2030 (patents) |
| Other DMD exons | 2025 (patent applications) 2030 (patents) |
| Exon-skipping | 2013 (patents) 2023 (patents) |
| Antivirals (Ebola, Marburg, Dengue and Influenza) | 2022 (patents) 2030 (patent applications) |
| Chemistry (PPMO, PMO*plus*® and PMO-X) | 2024 (patents) 2032 (patent applications) |
| Antibacterials | 2018 (patents) 2031 (patent applications) |
| Other rare diseases | 2025 (patent applications) 2032 (patent applications) |
| Other targets and programs | 2019 (patents) 2032 (patent applications) |

Some of our patents on core technologies expired in 2008, including a patent for our basic PMO chemistry. However, as we continue to advance the research supporting our PMO-based technologies, we believe that the patented and likely patentable improvements we are developing will provide the necessary basis to develop and exclusively commercialize our products. We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or

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learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

We are the owner of federal trademark registrations for four registered trademarks in the United States: AVI BioPharma®, Cytoporter®, PMO*plus*® and NeuGene®. We have pending trademark applications in the United States for PMO-X , Sarepta and Sarepta Therapeutics . We are the owner of international trademark registrations for Kepler Pharmaceuticals® in the European Community, Australia, New Zealand, Mexico, Norway and Switzerland; however, we have decided to let these registrations for Kepler Pharmaceuticals® expire at the end of their terms and will not seek to renew them. We have licensed certain technology to supplement and support certain of our core technologies. We have certain obligations and minimum royalties under those agreements, which costs are not material to our business and can be terminated at our discretion with minimal notice.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

We do not have patents or patent applications in every jurisdiction where there is a potential commercial market for our product candidates. For each of our programs, our decision to seek patent protection in specific foreign markets, in addition to the United States, is based on many factors, including:

- our available resources;
- the number and types of patents already filed or pending;
- the likelihood of success of the product candidate;
- the size of the commercial market;
- the presence of a potential competitor in the market; and
- whether the legal authorities in the market effectively enforce patent rights.

We continually evaluate our patent portfolio and patent strategy and believe our owned and licensed patents and patent applications provide us with a competitive advantage; however, if markets where we do not have patents or patent applications become commercially important, our business may be adversely affected.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States, and tests used for determining the patentability of patent claims in all technologies are in flux. In addition, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued. For example, patents which may issue to us may be subjected to further governmental review that may ultimately result in the reduction of their scope of protection, and pending patent applications may have their requested breadth of protection significantly limited before being issued, if issued at all. The pharmaceutical, biotechnology and other life sciences patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that we own or have licensed or in third-party patents. Further, since publication of discoveries in scientific or patent literature often lags behind actual discoveries, there is no assurance that we were the first creator of inventions covered by our pending patent applications, or that we were the first to file patent applications for these inventions.

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**Government Regulation**

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act and its implementing regulations, regulates pharmaceutical products. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, withdrawal of approval of approved products, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, civil penalties and/or criminal prosecution.

***Drug Approval Process***

To obtain FDA approval of a product candidate, we must, among other things, submit data providing substantial evidence of safety and efficacy of the product, as well as detailed information on the manufacture and composition of the product candidate and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The steps required before a drug may be approved for marketing in the United States generally include the following, with exceptions noted in the section captioned Government Regulation Animal Rule :

- preclinical laboratory tests and animal tests;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication;
- the submission to the FDA of a NDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMP;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

Preclinical studies may include laboratory evaluations of the product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as described in the protocol submitted as part of the IND prior to that time. In this case, the trials are placed on clinical hold, and the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidate to healthy volunteers or participants under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements and state subject rights laws. Further, each clinical trial must be

reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical

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trial design, participant informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials typically are conducted in three sequential phases prior to approval, but the phases may overlap. A fourth, or post-approval, phase may include additional clinical studies. These phases generally include the following; however, in the rare disease space, the number of subjects involved in each phase can be significantly less than the general parameters set forth below:

*Phase I*. Phase I clinical trials involve the initial introduction of the drug into human subjects. These studies are designed to determine the safety of usually single doses of the compound and determine any dose limiting intolerance, as well as evidence of the metabolism and pharmacokinetics of the drug in humans. Phase I studies usually involve less than 100 subjects and are most commonly conducted in healthy adult volunteers.

*Phase II*. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Phase II studies usually involve patients with the disease under investigation and numbers may vary from several dozen to several hundred.

*Phase III*. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) studies, the clinical trial program will be expanded to further confirm clinical efficacy, optimal dosage and safety within an expanded patient population which may involve geographically dispersed clinical trial sites. Phase III studies usually include several hundred to several thousand patients. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA.

*Phase IV*. Phase IV clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

A company seeking marketing approval for a new drug in the United States must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. If the FDA finds deficiencies in the NDA, it may issue a complete response letter, which contains the conditions that must be met in order to secure final approval

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of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Resubmissions by the NDA sponsor in response to a complete response letter trigger new review periods of varying length (typically two to six months) based on the content of the resubmission. The FDA may also refer an application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

A sponsor may also seek approval of its drug candidates under programs designed to accelerate the FDA s review and approval of NDAs. For instance, a sponsor may seek FDA designation of a drug candidate as a fast track product. Fast track products are those products intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for such disease or condition. If fast track designation is obtained, the FDA may initiate early, frequent, communication and begin reviewing sections of an NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the remaining information. We were granted fast track status for eteplirsen in 2007 and we announced in September 2012 that the FDA granted fast track status for the development of both AVI-7288 and AVI-7537.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted and signed into law in 2012 amended the criteria for the fast track and accelerated approval pathways and, as a result, the pathways now shares many common eligibility criteria. FDASIA provides both sponsor companies and the FDA with greater flexibility with expedited regulatory mechanisms. The statute clarifies that a fast track product may be approved pursuant to an accelerated approval (Subpart H) or under the traditional approval process. In addition, FDASIA codified the accelerated approval pathway as separate and apart from fast track pathway, meaning that for drugs to be eligible for accelerated approval, they do not need to be designated under the fast track pathway. FDASIA reinforces FDA s authority to grant accelerated approval based on surrogate endpoints that are reasonably likely to predict clinical benefit, and provides for more expansive use of non-surrogate clinical endpoints by authorizing FDA to grant accelerated approval based on the use of clinical endpoints that can be measured earlier in the development process than irreversible morbidity or mortality, and that are reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. In determining whether to grant accelerated approval, the FDA must consider the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Approvals of this kind typically include requirements for appropriate post-approval Phase IV clinical trials. FDASIA retains this requirement and further requires those studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit. We are participating in an end of Phase II meeting with the FDA in the first quarter of 2013 to discuss the clinical results from our Phase IIb study of eteplirsen. Based on feedback from the meeting, we will make an initial determination regarding the most appropriate regulatory path for pursuing regulatory review and approval of eteplirsen. Our initial determination will be further informed by a subsequent Chemistry, Manufacturing and Controls, or CMC, meeting.

Additionally, FDASIA established a new, expedited regulatory mechanism referred to as breakthrough therapy designation. Breakthrough therapy designation, fast track, and accelerated approval are not mutually exclusive and are meant to serve different purposes. The breakthrough therapy designation is focused on expediting the development and review process and by itself does not create an alternate ground for product approval. A sponsor may seek FDA designation of a drug candidate as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA is required to issue guidance to implement this provision and,

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if deemed necessary, is required to amend its regulations by the end of 2014. We will continue to evaluate, with input from the FDA, applying for breakthrough therapy designation as one aspect of our regulatory approach.

Finally, drug candidates, upon submission of an NDA, may also be eligible for priority review, or review within a six month timeframe from the date a complete NDA is accepted for filing, if a sponsor shows that its drug candidate provides a significant improvement compared to marketed drugs.

We cannot be sure that any of our drug candidates will qualify for any of these expedited development, review and approval programs, or that, if a drug does qualify, that the product candidates will be approved, will be accepted as part of any such program or that the review time will be shorter than a standard review.

Often, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to:

- report certain adverse reactions to the FDA;
- submit annual and periodic reports summarizing product information and safety data;
- comply with certain requirements concerning advertising and promotional labeling for their products; and
- continue to have quality control and manufacturing procedures conform to cGMP after approval.

The FDA periodically inspects the sponsor s records related to safety reporting and/or manufacturing; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Many other countries and jurisdictions have similar drug development and regulatory review processes. We have conducted clinical trials in the United Kingdom and intend to submit for marketing approval in countries other than the United States. Therefore, we will have to comply with the legal and regulatory requirements in the countries where we conduct trials and submit for marketing approval.

***Animal Rule***

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to various hemorrhagic fever viruses, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as the Animal Rule, the approval of such products can be based on clinical data from trials in healthy human subjects that demonstrate adequate safety, and immunogenicity and efficacy data from adequate and well-controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the Animal Rule adds significant time, complexity and uncertainty to the testing and approval process. No animal model is established as predicting human outcomes in the prevention or treatment of any filovirus disease. We have yet to demonstrate the predictive value of our animal studies to the FDA s satisfaction. In addition, products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients. Only one novel medical countermeasures has been approved using this pathway to date. Three other countermeasures have been approved under the Animal Rule which were extensions of existing indications with

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human data to support efficacy. Additional clarity on animal rule requirements is not anticipated until later in 2013 when the FDA is expected to release an updated version of its draft guidance on the animal rule that was first published in January 2009.

***Emergency Use Authorization***

The Commissioner of the FDA, under delegated authority from the Secretary of DHHS may, under certain circumstances, issue an Emergency Use Authorization, or EUA, that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;
- a determination by the Secretary of DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent of agents; or
- a determination by the Secretary of DHHS of a public health emergency that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a disease attributable to the agents described above; that the product s potential benefits outweigh its potential risks; and that there is no adequate, approved alternative to the product.

Although an EUA cannot be issued until after an emergency has been declared by the Secretary of DHHS, the Agency strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA Center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited. We intend to work with DoD in the future on pre-EUA submissions with respect to our product candidates intended to treat Marburg and Ebola in order to inform and expedite the FDA s issuance of an EUA, should one become necessary in the event of an emergency.

***Orphan Drug Designation and Exclusivity***

Some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies. If a product which has an orphan

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drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to an orphan drug exclusivity period, which means the FDA may not grant approval to any other application to market a different drug for the same indication for a period of seven years, except in limited circumstances, such as where an alternative product demonstrates clinical superiority to the product with orphan exclusivity. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug. An additional six months of exclusivity may be granted to a sponsor of an NDA, if the sponsor conducted a pediatric study or studies of such product. This process is initiated by the FDA as a written request for pediatric studies that applies to sponsor s product. If the sponsor conducts qualifying studies and the studies are accepted by the FDA, then an additional six months of pediatric exclusivity will attach to any other regulatory exclusivity or patent protection applicable to any drug product containing the same active moiety as the drug studied and for which the party submitting the studies holds the NDA. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity. We have been granted orphan drug designation for eteplirsen and AVI-5038 in the United States and European Union.

The European Orphan Drug Regulation is considered for drugs intended to diagnose, prevent or treat a life-threatening or very serious condition afflicting five or fewer out of 10,000 people in the EU, including compounds that for serious and chronic conditions would likely not be marketed without incentives due to low market return on the sponsor s development investment. The medicinal product considered should be of significant benefit to those affected by the condition. Benefits of being granted orphan drug designation are significant, including eight years of data exclusivity, two years of marketing exclusivity and a potential one year extension of both. The EU Community and Member States may not accept or grant for ten years a new marketing authorization or application for another drug for the same therapeutic indication as the orphan drug, although the ten year period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. A supplementary protection certificate may extend the protection six months beyond patent expiration if that is later than the orphan drug exclusivity period. To apply for the supplementary protection, a pediatric investigation plan, or PIP, must be included in the market application. In Europe all drugs now seeking a marketing authorization need to have a PIP agreed with the EMA before it can be approved, even if it is a drug being developed specifically for a pediatric indication. If a product is developed solely for use in the pediatric population, then a Pediatric Use Marketing Authorization, or PUMA, may provide eight years of data exclusivity and ten years of marketing exclusivity. This PUMA applies to our DMD compounds, eteplirsen and AVI-5038.

***Other Regulatory Requirements***

In addition to regulation by the FDA and certain state regulatory agencies, we are also subject to a variety of foreign regulations governing clinical trials and the marketing of other products. Outside of the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

**Pharmaceutical Pricing and Reimbursement**

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such

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as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third-party payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with the availability of such studies, our products may be considered less safe, less effective or less cost-effective than alternative products, and third-party payers may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business, including the Patient Protection and Affordable Care Act of 2010. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for drugs;
- mandatory discounts under certain government sponsored programs;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws; and
- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business prospects.

**Competition**

The pharmaceutical and biotechnology industries are intensely competitive, and any product candidate developed by us would likely compete with existing drugs and therapies. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of rare and infectious diseases. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Several of them have developed or are developing therapies that could be used for treatment of the same diseases that we are targeting. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on:

- our ability to complete clinical development and obtain regulatory approvals for our product candidates;
- the efficacy, safety and reliability of our product candidates;

the timing and scope of regulatory approvals;

product acceptance by physicians and other health care providers;

protection of our proprietary rights and the level of generic competition;

the speed at which we develop product candidates;

our ability to supply commercial quantities of a product to the market;

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obtaining reimbursement for product use in approved indications;

our ability to recruit and retain skilled employees; and

the availability of substantial capital resources to fund development and commercialization activities, including the availability of funding from the U.S. Government.

*DMD Program Competition*. Currently, no product has been approved for the treatment of DMD. Companies including, but not limited to, Prosensa in collaboration with GlaxoSmithKline plc, or GSK, have product candidates in development for the treatment of DMD.

The Prosensa / GSK program commenced treatment in December 2010 in a Phase III clinical study in ambulant individuals with DMD who have a dystrophin gene mutation amenable to treatment by skipping exon 51. Prosensa s candidate for skipping exon 51, GSK2402968, utilizes a different chemistry, 2 O-methyl-phosphorothioate, which has the potential for different performance, safety and tolerability characteristics than eteplirsen. This randomized, placebo controlled study is fully enrolled, with approximately 180 participants who are being dosed for 48 weeks. The primary efficacy endpoint is a measure of muscle function using the 6MWT. Results for this Phase III study are anticipated by the end of 2013. In September 2010, the Prosensa / GSK program commenced a Phase II double-blind, placebo-controlled study. This study is designed to assess the efficacy of two different dosing regimens of GSK2402968 administered over 24 weeks in DMD patients, and then to continue observing the patients over a second 24 week interval for a total study time frame of 48 weeks. This study completed enrollment with 54 DMD patients in October 2011 and has since concluded with results expected after the Phase III clinical study is complete. Another study using GSK2402968 in non-ambulatory DMD patients has been initiated using a 6 mg/kg dose and is anticipated to enroll 20 patients. These studies may or may not prove that GSK2402968 is safer and more efficacious than eteplirsen; however, data obtained from these studies could aid Prosensa / GSK in obtaining marketing approval before our lead DMD product candidate eteplirsen.

*Hemorrhagic Fever Virus Programs*. No specific treatment has been proven effective, and no approved vaccine currently exists for either Ebola or Marburg. Investigational compounds cannot be tested for efficacy on humans except in outbreak environments so these agents must be tested extensively in animals and meet strict government regulations. Vaccine development is in the early stages in both the biotech industry and by U.S. government agencies (*e.g.*, the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention). The government is also supporting early stage research on broad-spectrum therapeutics effective against hemorrhagic fever viruses. With respect to therapeutics in advanced development, February 2012, Tekmira Pharmaceuticals Corp. initiated a Phase I trial for TKM-Ebola, a systemically delivered RNAi therapeutic for the treatment of Ebola virus infection. We commenced initial human safety studies of our therapeutic candidates against Marburg and Ebola viruses in May 2011.

*Influenza Program*. Currently, there are two therapeutic products for influenza that have received market approval from the FDA and are recommended for use in the United States. These are: (1) oseltamivir (Tamiflu), a Roche Holding and Gilead product; and (2) zanamivir (Relenza), a GSK product. In addition to these products, Daiichi Sankyo s laninamivir and BioCryst s peramivir were launched in 2010 in Japan. Currently, DHHS funding is helping support clinical trials of Biota s laninamivir. In addition, other companies including, Toyama Chemical (a subsidiary of Fujifilm), have influenza therapeutic compounds in development. Toyama Chemical s favipiravir is in a Phase II clinical trial in the United States and has completed a Phase III trial in Japan. DHHS is currently seeking additional antiviral therapeutics for the treatment and/or prophylaxis of influenza A and B infections.

In addition to therapeutic products, other companies are focusing development efforts on universal influenza vaccines, including BiondVax Pharmaceuticals Ltd., which initiated a Phase IIa trial of its universal influenza vaccine candidate in October 2010. Successful development of a universal influenza vaccine could lead to a reduction in the number of influenza cases and, therefore, the market size.

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*Platform Technology*. We believe that other biotechnology and pharmaceutical companies share a focus on RNA-based drug discovery and development. Competitors with respect to our RNA-based technologies include, but are not limited to, Alnylam Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corp., Isis Pharmaceuticals, Inc., Prosensa, Sanofi Aventis, and Santaris Pharma A/S. We are unaware of any other commercial organization that is developing therapeutics based on a PMO chemistry platform.

**Research and Development**

We devote a substantial portion of our resources to developing new product candidates. During 2012, 2011 and 2010, we expended approximately $52.4 million, $66.9 million and $36.0 million, respectively, on research and development activities.

**Employees**

As of December 31, 2012, we had 103 employees, 39 of which hold advanced degrees. Of these employees, 64 are engaged directly in research and development activities and 39 are in administration. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

## Item 1A. Risk Factors.

**Factors That Could Affect Future Results**

*Set forth below and elsewhere in this Annual Report on Form 10-K and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Annual Report on Form 10-K. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also affect our results of operations and financial condition.*

**Risks Relating to Our Business**

***Our product candidates are at an early stage of development, and it is possible that none of our product candidates will ever become commercial products.***

Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, eteplirsen in DMD, AVI-7288 in Marburg and AVI-7100 in influenza are in active clinical development. AVI-7537 in Ebola was in active clinical development until August 2012, when we received a stop-work order from DoD instructing us to cease all work and ordering of supplies in support of the development of this product candidate. On October 2, 2012, we received notice from DoD that the program for the development of AVI-7537 was terminated for the convenience of the government due to funding constraints. The rest of our product candidates are in preclinical development. We expect that much of our effort and many of our expenditures over the next several years will be devoted to development activities associated with eteplirsen and other exon-skipping candidates as part of our larger pan-exon strategy in DMD, our infectious disease candidates, our proprietary chemistry, and other potential therapeutic areas that provide long-term market opportunities. With current resources, we may be restricted or delayed in our ability to develop these and other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including eteplirsen, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval, (including any accelerated approval by the FDA under Subpart H Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) or any other designations that will expedite the review or approval process for any of our

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product candidates, based on an inability to adequately demonstrate the safety and effectiveness of our product candidates, failure to meet other regulatory requirements, lack of funding, changes in the regulatory landscape, manufacturing or other reasons. If we are unable to obtain approval for any of our product candidates it could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Assuming that any of our product candidates receives the required regulatory approvals, commercial success will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety and acceptance of the same by the medical community;
- sufficient commercial supply of the product;
- cost-effectiveness of the product;
- the availability of adequate reimbursement by third parties, including governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers;
- the product s potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs;
- marketing and distribution support for the product; and
- any exclusivities applicable to the product.

To date we have been granted orphan status for two of our product candidates in DMD and for AVI-7537 for the treatment of Ebola virus and AVI-7288 for the treatment of Marburg virus. We are not guaranteed to receive orphan status for other product candidates in development or product candidates we may develop in the future. Even though we have received orphan status for some of our product candidates, we would not enjoy orphan drug exclusivity for such product candidates in the event that another entity received approval of products with the same active ingredient for the same indication before we receive market approval (assuming no exceptions to the grant of orphan drug status to additional product candidates were to apply). Further, application of the orphan drug regulations in the United States and Europe is uncertain and we cannot predict how the respective regulatory bodies will interpret and apply the regulations to our or our competitors product candidates. If a competitor s product receives orphan drug designation for an indication that we are targeting, and such product is approved for commercial sales before our product, regulators may interpret our product to be the same drug as the competing product and could prevent us from selling our product in the applicable territories for the competitors orphan exclusivity period. Furthermore, pediatric exclusivity only applies if the product has another form of exclusivity.

If we are unable to develop and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never reach sustained profitability.

***If we are unable to obtain or maintain required regulatory approvals, we will not be able to commercialize our product candidates, our ability to generate revenue will be materially impaired and our business may not be successful.***

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States, and other regulatory authorities in other countries, with regulations differing from country to country.

Marketing of our product candidates in the United States or foreign countries is not permitted until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we may never receive regulatory approval for the commercial sale of any of our

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product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured. As of the date of this report, we have not progressed to the point of preparing or filing the applications necessary to gain regulatory approvals.

Further, the FDA and other foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval, of any type, will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising and our CMC and related manufacturing processes are satisfactory, the FDA or foreign authorities may disagree with our interpretations and determine such data is not sufficient to accept out application or support approval. Furthermore, regulatory agencies may approve a product candidate for fewer indications or for a more narrowly defined indication than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols or other approval strategies to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or the FDA for review, which may impact the costs, timing or successful completion of a clinical trial. Changes in our approval strategies may occur that require additional studies that were not originally planned. Other factors may also impact our ability to obtain approval and commercialize our product candidates, including, for example, the fact that a therapeutic commercial product utilizing our RNA-based technologies and the manufacturing techniques necessary to produce them at commercial scale have never been approved or validated by any regulatory authority. Due to these factors, among others, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

For example, we are pursuing FDA approval of eteplirsen, our lead product candidate, and recently reported results from a U.S. based Phase IIb 12-patient clinical trial for eteplirsen at 30 mg/kg and 50 mg/kg. Based on feedback from an end of Phase II meeting with the FDA, we will make an initial determination regarding the most appropriate path for pursuing regulatory review and approval of eteplirsen. Our initial decision will be further informed by a subsequent CMC, meeting. There can be no assurance that after our evaluation of the feedback and minutes from the end of Phase II meetings with the FDA that we will decide to pursue or submit an NDA under Subpart H accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback and CMC meetings that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (*e.g.*, breakthrough therapy designation), there can be no assurance that such submission or application will be accepted (*e.g.*, refusal to file) or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other foreign authorities could also require us conduct further studies or CMC related work (*e.g.*, a complete response letter) prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for eteplirsen or any of our other product candidates (i) would result in a longer time period for commercialization of such product candidate, (ii) could potentially increase the cost of development of such product candidate and (iii) could harm our competitive position in the marketplace.

Additionally, even if we receive regulatory approval for our product candidates, we will be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and, potentially, other post-marketing obligations such as confirmatory studies, all of which may result in significant expense and limit our ability to commercialize such products. The FDA s policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature

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or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States, or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in, or failure to, receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability. We will also need to obtain regulatory approval from regulatory authorities in foreign countries to market our product candidates in those countries. We have not submitted an application for regulatory approval to market our product candidates in any foreign jurisdiction. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

***Our preclinical and clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.***

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical and clinical studies that the product candidate is safe and effective in humans. Ongoing and future preclinical and clinical trials of our product candidates may not show sufficient safety or efficacy to obtain regulatory approvals.

In 2012 we completed Study 201, a U.S. based Phase IIb 12 person clinical trial for eteplirsen at 30 mg/kg and 50 mg/kg. Following completion of this study, we initiated Study 202, an ongoing open label extension study with the same participants from Study 201. These trials were initiated, in part, to further demonstrate efficacy and safety, including the production of dystrophin, and explore and identify a more consistently effective dose that may be more appropriate for future clinical trials. While Studies 201 and 202 met their primary endpoints at weeks 24 and 48 respectively, we cannot assure you that data from these studies will be sufficient for regulatory approval or that Study 202 extension study results will continue to be positive through the remaining study period. If these data are not sufficient to demonstrate safety and efficacy to regulators, do not continue to demonstrate safety and efficacy through the remainder of Study 202, or are insufficient to identify a consistently effective dose, we expect we will need to engage in discussions with regulatory authorities about the design and subsequent execution of any further studies which may be required. Regulatory authorities might require more extensive preclinical or clinical trials than anticipated. Such clinical trials might include additional open label extension studies for all participants who have previously received eteplirsen, as well as other participants (*e.g.*, non-ambulatory participants), additional placebo-controlled pivotal study or studies, or additional trials before conducting a pivotal trial or trials of the product. Any additional studies required by regulatory authorities would increase our costs and delay commercialization of eteplirsen and any of our other product candidates. Even if we conform to any guidance regulatory authorities provide it does not guarantee receipt of marketing approval, even if we believe our preclinical and clinical trials are successful.

Furthermore, success in preclinical and early clinical trials does not ensure that the ongoing Study 202 and later larger-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be reproduced in the remainder of the Study 202 extension study or later trials. For example, pivotal trials for eteplirsen will likely involve a larger number of patients to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.

***We currently rely on certain third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the advancement of our research and development programs and the development of our product candidates.***

We do not currently have the internal ability to manufacture the product candidates in the quantities that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our product

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candidates and the components of our drug substance. We may also need to rely on manufacturers for the production of our product candidates to support our research and development programs. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling and labeling of vials and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce product candidates and their components, fill vials, and store sufficient quantities of our product candidates for research and development programs, clinical trials and potential commercial supply. For each of our eteplirsen, Marburg and other development programs, based on limited capacity for our specialized manufacturing needs we have had to enter into limited or, at times, sole-source agreements with multinational manufacturing firms for the production of the APIs for eteplirsen, Marburg and other therapeutics. There are a limited number of companies that can produce APIs in the quantities and with the quality and purity that we require. Establishing a relationship with alternative suppliers can be a lengthy process and might cause delays in our development efforts. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

Our product candidates require precise, high-quality manufacturing. The failure to achieve and maintain high quality standards, including failure to detect or control anticipated or unanticipated manufacturing errors could result in patient injury or death or product recalls. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. If our contract manufacturers or other third parties fail to deliver our product candidates for our research and development programs, clinical use or potential commercial supply on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials, research and development programs, commercial supply or otherwise discontinue development and production of our product candidates. In addition, we currently depend on certain third-party vendors, which in some cases may be sole sources, for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with sufficient quantities of quality raw materials and we are unable to contract on acceptable terms for these raw materials with alternative suppliers, if any, our ability to have our product candidates manufactured in sufficient quantities for preclinical testing, clinical trials, and potential commercial use would be adversely affected.

We do not yet have all of the agreements necessary for the supply of APIs and raw materials for the production of any of our product candidates in quantities sufficient for commercial sale and we may not be able to establish or maintain sufficient commercial manufacturing arrangements on commercially reasonable terms. Securing commercial quantities of our product candidates and their components from contract manufacturers will require us to commit significant capital and resources. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers have a limited number of facilities in which our product candidates can be produced and any interruption of the development or operation of those facilities due to events such as order delays for equipment or materials, equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates or materials.

Our contract manufacturers are required to produce our clinical product candidates under cGMP conditions in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer s compliance with these regulations and standards. Any difficulties or delays in our contractors

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manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, make us postpone or cancel clinical trials, prevent or delay regulatory approval by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our product candidates, or cause our products to be recalled or withdrawn.

***We may not be able to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing resulting approved drug products, if any.***

To date, our product candidates have been manufactured in small quantities for preclinical studies and early stage clinical trials. As we prepare for later stage clinical trials in eteplirsen and potential commercialization, we are working to increase the scale of production of our drug product and planning for mid-scale production in the first half of 2013. In 2013, we will also evaluate whether to increase API production capacity to a commercial scale which will depend in significant part on feedback from the FDA and our expectations regarding if and when we would commence a pivotal trial for eteplirsen and potential commercialization. In order to conduct larger or late-stage scale clinical trials for a product candidate and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our product candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. If a contract manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to those improvements. Significant scale-up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up manufacture of any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed or there may be a shortage in supply, which could significantly harm our business.

In addition, in order to release product and demonstrate stability of product candidates for use in late stage clinical trials (and any resulting drug products for commercial use), our analytical methods must be validated in accordance with regulatory guidelines. We may not be able to successfully validate our analytical methods or demonstrate adequate stability of the product candidates in a timely or cost-effective manner or at all. If we are unable to successfully validate our analytical methods or to demonstrate adequate stability, the development of our product candidates and regulatory approval or commercial launch for any resulting drug products may be delayed, which could significantly harm our business.

***We rely on U.S. government contracts to support certain research and development programs and substantially all of our revenue. If the U.S. government fails to fund such programs on a timely basis or at all, or such contracts are terminated, the results of our operations would be materially and adversely affected.***

We rely on U.S. government contracts and awards to fund and support certain development programs, including the Marburg virus which accounts for substantially all of our current revenue. The funding of U.S. government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may extend over several fiscal years, as is the case with our DoD contract for the development of our Marburg product candidate. Consequently, programs are often only partially funded initially and additional funds are committed only as Congress makes further appropriations. If appropriations for one of our programs become unavailable as was the case in 2012 with regards to the Ebola portion of our July 2010 Agreement for the development of therapeutics against the Ebola and Marburg viruses,

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or are reduced or delayed, our contracts may be terminated or adjusted by the government, which could have a negative impact on our future revenue under such contract or subcontract. From time to time, when a formal appropriation bill has not been signed into law before the end of the U.S. government s fiscal year, Congress may pass a continuing resolution that authorizes agencies of the U.S. government to continue to operate, generally at the same funding levels from the prior year, but does not authorize new spending initiatives, during a certain period. During such a period, or until the regular appropriation bills are passed, delays can occur in government procurement due to lack of funding and such delays can affect our operations during the period of delay. Currently DOD is operating under a Continuing Resolution for FY 2013. Additionally, on March 1, 2013, a sequestration went into effect which implements across-the-board cuts to government agencies, totaling $1.2 trillion over 10 years. These cuts are to be split 50-50 between domestic and defense discretionary spending. DoD must make $47 billion in cuts before September 30, 2013. These cuts could have widespread ramifications including on DoD s procurement and research and development programs. Sequestration may result in a reduction of funds availablttom:0pt'**>4,758**

$

4,650

Other comprehensive income/loss, net of tax:

Unrealized gain/(loss) on available for sale securities

**600**

(1,495

)

**TOTAL COMPREHENSIVE INCOME**

**$**

**5,358**

$

3,155

**BASIC WEIGHTED AVERAGE COMMON SHARES**

**12,159,768**

12,013,830

**BASIC EARNINGS PER COMMON SHARE**

**$**

**0.39**

$

0.39

**DILUTED WEIGHTED AVERAGE COMMON SHARES**

**12,419,975**

12,340,770

**DILUTED EARNINGS PER COMMON SHARE**

**$**

**0.38**

$

0.38

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKELAND FINANCIAL CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**For the Three Months Ended March 31, 2007 and 2006**

**(in thousands)**

**(Unaudited)**

**(Page 1 of 2)**

| | **2007** | **2006** |
|---|---|---|
| Cash flows from operating activities: | | |
| Net income | **$ 4,758** | $ 4,650 |
| Adjustments to reconcile net income to net cash from operating activities: | | |
| Depreciation | **410** | 420 |
| Provision for loan losses | **641** | 453 |
| Amortization of intangible assets | **51** | 52 |
| Amortization of loan servicing rights | **108** | 117 |
| Net change in loan servicing rights valuation allowance | **(18)** | (27) |
| Loans originated for sale | **(11,435)** | (7,713) |
| Net gain on sales of loans | **(165)** | (152) |
| Proceeds from sale of loans | **12,595** | 7,150 |
| Net (gain) loss on sale of premises and equipment | **(4)** | 1 |
| Net gain on sales of securities available for sale | **(36)** | (2) |
| Net securities amortization | **239** | 340 |
| Stock compensation expense | **45** | 13 |
| Earnings on life insurance | **(171)** | (176) |
| Net change: | | |
| Accrued income receivable | **421** | 110 |
| Accrued expenses payable | **2,572** | 2,407 |
| Other assets | **(101)** | (82) |
| Other liabilities | **101** | (63) |
| Total adjustments | **5,253** | 2,848 |
| Net cash from operating activites | **10,011** | 7,498 |
| | | |
| Cash flows from investing activities: | | |
| Proceeds from sale of securities available for sale | **$ 13,530** | $ 8,405 |
| Proceeds from maturities, calls and principal paydowns of securities available for sale | **8,798** | 12,269 |
| Purchases of securities available for sale | **(23,668)** | (23,112) |
| Purchase of life insurance | **(112)** | (110) |
| Net increase in total loans | **(24,435)** | (26,440) |
| Proceeds from sales of land, premises and equipment | **60** | 43 |
| Purchases of land, premises and equipment | **(699)** | (272) |
| Net cash from investing activities | **(26,526)** | (29,217) |

(Continued)

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**LAKELAND FINANCIAL CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**For the Three Months Ended March 31, 2007 and 2006**

**(in thousands)**

**(Unaudited)**

**(Page 2 of 2)**

| | **2007** | **2006** |
|---|---|---|
| Cash flows from financing activities: | | |
| Net increase in total deposits | **22,237** | 53,500 |
| Net increase (decrease) in short-term borrowings | **(47,999 )** | (48,845 ) |
| Payments on long-term borrowings | **(1 )** | (1 ) |
| Dividends paid | **(1,516 )** | (1,376 ) |
| Proceeds from stock option exercise | **870** | 828 |
| Purchase of treasury stock | **(113 )** | (88 ) |
| Net cash from financing activities | **(26,522 )** | 4,018 |
| Net change in cash and cash equivalents | **(43,037 )** | (17,701 ) |
| Cash and cash equivalents at beginning of the period | **119,699** | 82,679 |
| Cash and cash equivalents at end of the period | **$ 76,662** | $ 64,978 |
| Cash paid during the period for: | | |
| Interest | **$ 13,174** | $ 9,768 |
| Income taxes | **0** | 75 |

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKELAND FINANCIAL CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2007**

**(In thousands)**

**(Unaudited)**

**NOTE 1. BASIS OF PRESENTATION**

This report is filed for Lakeland Financial Corporation (the Company ) and its wholly-owned subsidiary, Lake City Bank (the Bank ). All significant inter-company balances and transactions have been eliminated in consolidation. Also included is the Bank s wholly-owned subsidiary, LCB Investments II, Inc. ( LCB Investments ). LCB Investments also owns LCB Funding, Inc. ( LCB Funding ), a real estate investment trust.

The unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with instructions for Form 10-Q. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (all of which are normal and recurring in nature) considered necessary for a fair presentation have been included. Operating results for the three-month period ending March 31, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. The 2006 Lakeland Financial Corporation Annual Report on Form 10-K should be read in conjunction with these statements.

**NOTE 2. EARNINGS PER SHARE**

Basic earnings per common share is net income divided by the weighted average number of common shares outstanding during the period. Diluted earnings per common share includes the dilutive effect of additional potential common shares issuable under stock options. Earnings and dividends per share are restated for all stock splits and dividends through the date of issue of the financial statements. The common shares included in Treasury Stock for 2007 and 2006 reflect the acquisition of 91,332 and 86,785 shares, respectively of Lakeland Financial Corporation common stock that have been purchased under a directors deferred compensation plan. Because these shares are held in trust for the participants, they are treated as outstanding when computing the weighted-average common shares outstanding for the calculation of both basic and diluted earnings per share.

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**NOTE 3. LOANS**

| | March 31, 2007 | December 31, 2006 |
|---|---|---|
| Commercial and industrial loans | $ 990,404 | $ 946,767 |
| Agri-business and agricultural loans | 117,169 | 139,644 |
| Real estate mortgage loans | 107,236 | 100,540 |
| Real estate construction loans | 6,578 | 8,636 |
| Installment loans and credit cards | 156,628 | 158,310 |
| Subtotal | 1,378,015 | 1,353,897 |
| Less: Allowance for loan losses | (14,758) | (14,463) |
| Net deferred loan fees | (89) | (60) |
| Loans, net | $ 1,363,168 | $ 1,339,374 |
| | | |
| Impaired loans | $ 13,226 | $ 13,333 |
| | | |
| Non-performing loans | $ 13,772 | $ 14,119 |
| | | |
| Allowance for loan losses to total loans | 1.07% | 1.07% |

Changes in the allowance for loan losses are summarized as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2007 | 2006 |
| Balance at beginning of period | $ 14,463 | $ 12,774 |
| Provision for loan losses | 641 | 453 |
| Charge-offs | (458) | (33) |
| Recoveries | 112 | 42 |
| Net loans charged-off | (346) | 9 |
| Balance at end of period | $ 14,758 | $ 13,236 |

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**NOTE 4. SECURITIES**

The fair values of securities available for sale were as follows:

| | March 31, 2007 | December 31, 2006 |
|---|---|---|
| U.S. Treasury securities | $ 1,173 | $ 965 |
| U.S. Government agencies | 33,634 | 30,525 |
| Mortgage-backed securities | 209,119 | 210,000 |
| State and municipal securities | 54,343 | 54,701 |
| Total | $ 298,269 | $ 296,191 |

As of March 31, 2007, net unrealized losses on the total securities available for sale portfolio totaled $2.0 million. As of December 31, 2006, net unrealized losses on the total securities available for sale portfolio totaled $2.9 million. Management considers the unrealized losses to be market driven and no loss is expected to be realized unless the securities are sold. All of the securities are backed by the U.S. Government, government agencies, government sponsored agencies or are A rated or better, except for certain non-local municipal securities. None of the securities have call provisions (with the exception of the municipal securities) and payments as originally agreed are being received. There are no concerns of credit losses and there is nothing to indicate that full principal will not be received. Management considers the unrealized losses to be market driven, and no loss is expected to be realized unless the securities are sold. The Company does not have a history of actively trading securities, but keeps the securities available for sale should liquidity or other needs develop that would warrant the sale of securities. While these securities are held in the available for sale portfolio, the current intent and ability is to hold them until a recovery in fair value or maturity.

**NOTE 5. EMPLOYEE BENEFIT PLANS**

Components of Net Periodic Benefit Cost

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | Pension Benefits | | SERP Benefits | |
| | 2007 | 2006 | 2007 | 2006 |
| Service cost | $ 0 | $ 0 | $ 0 | $ 0 |
| Interest cost | 35 | 36 | 19 | 19 |
| Expected return on plan assets | (43) | (42) | (23) | (23) |
| Recognized net actuarial loss | 11 | 11 | 14 | 13 |
| Net pension expense | $ 3 | $ 5 | $ 10 | $ 9 |

The Company previously disclosed in its financial statements for the year ended December 31, 2006 that it expected to contribute $35,000 to its pension plan and $59,000 to its SERP plan in 2007. As of March 31, 2007, $59,000 had been contributed to the SERP plan and $0 to the pension plan. The Company presently anticipates contributing $35,000 to its pension plan in 2007.

**NOTE 6. NEW ACCOUNTING PRONOUNCEMENTS**

The Company adopted FASB Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 , on January 1, 2007. FIN 48 requires that realization of an uncertain income tax position be more likely than not before it can be recognized in the financial statements. Further, FIN 48 prescribes the benefit to be recorded in the financial statements as the largest amount more likely than not to be realized assuming a review by tax authorities having all relevant information and applying current conventions. FIN 48 also clarifies the financial statement classification of tax-related penalties and interest and sets forth new disclosures regarding unrecognized tax benefits. The adoption of this standard did not have an impact on the financial statements of the Company. Should the accrual of any interest or penalties relative to unrecognized tax benefits be necessary, it is the Company s policy to record such accruals in its income taxes accounts; no such accruals exist as of January 1, 2007. The Company and its subsidiaries file a consolidated U.S. federal income tax return and a combined unitary return in the state of Indiana. These returns are subject to examinations by taxing authorities for all years after 2002.

The Company adopted FASB Statement of Financial Accounting Standards No. 156 (SFAS No. 156), *Accounting for Servicing of Financial Assets - an amendment of FASB Statement No. 140*, on January 1, 2007. SFAS No. 156 requires the recognition of a servicing asset or servicing liability when entering into a servicing contract to service a financial asset and requires all separately recognized servicing assets and liabilities to be initially measured at fair value. Further SFAS No. 156 permits a choice of subsequent measurement methods for each class of separately recognized servicing assets and servicing liabilities between the current amortization method and the fair value measurement method. At initial adoption, SFAS No. 156 permits a one time reclassification of available for sale securities to trading securities by entities with recognized servicing rights, without calling into question the treatment of other available for sale securities under Statement 115, provided the securities are identified in some manner as offsetting the exposure to changes in fair value of servicing assets or servicing liabilities that are subsequently measured at fair value. Finally, SFAS No. 156 requires separate presentation of servicing assets and servicing liabilities subsequently measured at fair value in the statement of financial position and additional disclosures for all separately recognized servicing assets and servicing liabilities. The adoption of SFAS No. 156 did not have a material impact on the Company s financial statements.

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 159 (SFAS No. 159), The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. This statement also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company will adopt SFAS No. 159 on January 1, 2008, and does not expect the adoption to have a material impact on the financial statements.

**NOTE 7. RECLASSIFICATIONS**

Certain amounts appearing in the financial statements and notes thereto for prior periods have been reclassified to conform with the current presentation. The reclassification had no effect on net income or stockholders equity as previously reported.

**Part 1**

**LAKELAND FINANCIAL CORPORATION**

**ITEM 2 - MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION**

**and**

**RESULTS OF OPERATIONS**

**March 31, 2007**

**OVERVIEW**

Lakeland Financial Corporation is the holding company for Lake City Bank. The Company is headquartered in Warsaw, Indiana and operates 43 offices in 12 counties in northern Indiana. The Company earned $4.8 million for the first three months of 2007, versus $4.7 million in the same period of 2006, an increase of 2.3%. The increase was driven by a $238,000 increase in net interest income as well as an increase of $63,000 in noninterest income. Offsetting these positive impacts was an increase of $378,000 in noninterest expense as well as an increase of $188,000 in the provision for loan losses. Basic earnings per share for the first three months of 2007 and 2006 were $0.39 per share. Diluted earnings per share reflect the potential dilutive impact of stock options granted under the stock option plan. Diluted earnings per share for the first three months of 2007 and 2006 were $0.38 per share.

**RESULTS OF OPERATIONS**

**Net Interest Income**

For the three-month period ended March 31, 2007, net interest income totaled $13.1 million, an increase of 1.9%, or $238,000, versus the first three months of 2006. Net interest income increased in the three-month period of 2007 versus the comparable period of 2006, primarily due to a $160.6 million, or 10.7%, increase in average earning assets to $1.665 billion.

Given the Company s mix of interest earning assets and interest bearing liabilities at March 31, 2007, the Company would generally be considered to have a slightly asset-sensitive balance sheet, although the current interest rate environment has countered the asset-sensitive nature of the balance sheet. An asset-sensitive balance sheet structure would normally be expected to produce a stable or improving net interest margin in a rising rate environment. As the Company s balance sheet has become more neutral in structure, management believes that future rate movements will have less impact on net interest margin than historically. In addition, the Company s mix of deposits has shifted to more reliance on certificates of deposits, specifically public fund deposits and brokered deposits, which generally carry a higher interest rate cost than other types of interest bearing deposits.

During the first three months of 2007, total interest and dividend income increased by $4.3 million, or 17.9%, to $28.3 million, versus $24.0 million during the first three months of 2006. This increase was primarily the result of an increase in average earning assets, as well as general increases in interest rates. The tax equivalent yield on average earning assets increased by 41 basis points to 7.0% for the three-month period ended March 31, 2007 versus the same period of 2006.

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During the first three months of 2007, loan interest income increased by $4.0 million, or 19.5%, to $24.7 million, versus $20.7 million during the first three months of 2006. The increase was driven by a $147.5 million, or 12.2%, increase in average daily loan balances, as well as a 45 basis point increase in the tax equivalent yield on loans to 7.4%, versus 7.0% in the first three months of 2006.

The average daily securities balances for the first three months of 2007 increased $4.1 million, or 1.4%, to $295.7 million, versus $291.6 million for the same period of 2006. During the same periods, income from securities increased by $112,000, or 3.5%, to $3.3 million versus $3.2 million during the first three months of 2006. The increase was primarily the result of a 6 basis point increase in the tax equivalent yield on securities, to 4.9% versus 4.8% in the first three months of 2006.

Total interest expense increased $4.0 million, or 36.4%, to $15.2 million for the three-month period ended March 31, 2007, from $11.1 million for the comparable period in 2006. The increase was primarily the result of a 77 basis point increase in the Company s daily cost of funds to 3.8%, versus 3.0% for the same period of 2006. Increases in total deposits also contributed to increases in total interest expense over the three-month period.

On an average daily basis, total deposits (including demand deposits) increased $179.0 million, or 14.0%, to $1.454 billion for the three-month period ended March 31, 2007, versus $1.275 billion during the same period in 2006. On an average daily basis, non-interest bearing demand deposits decreased to $216.5 million for the three-month period ended March 31, 2007, versus $216.9 million for the same period in 2006. On an average daily basis, interest bearing transaction accounts increased $20.9 million, or 6.0%, to $370.2 million for the three-month period ended March 31, 2007, versus the same period in 2006. When comparing the three months ended March 31, 2007 with the same period of 2006, the average daily balance of time deposits, which pay a higher rate of interest compared to demand deposit and transaction accounts, increased $160.1 million, primarily as a result of increases in public fund deposits and certificates of deposit of $100,000 or more. The rate paid on time deposit accounts increased 93 basis points to 5.1% for the three-month period ended March 31, 2007, versus the same period in 2006.

Due to strong loan growth and additional relationship opportunities, the Company continues to focus on public fund deposits as a core funding strategy. In addition, the Company has introduced brokered certificates of deposit to the funding mix as a result of loan growth. On an average daily basis, total brokered certificates of deposit increased $18.1 million to $90.8 million for the three-month period ended March 31, 2007, versus $72.7 million for the same period in 2006. On an average daily basis, total public fund certificates of deposit increased $56.2 million to $291.8 million for the three-month period ended March 31, 2007, versus $235.6 million for the same period in 2006.

Average daily balances of borrowings were $170.9 million during the three months ended March 31, 2007, versus $216.9 million during the same period of 2006, and the rate paid on borrowings increased 47 basis points to 4.9%. On an average daily basis, total deposits (including demand deposits) and purchased funds increased 3.8%, when comparing the three-month period ended March 31, 2007 versus the same period in 2006. The following tables set forth consolidated information regarding average balances and rates:

DISTRIBUTION OF ASSETS, LIABILITIES AND STOCKHOLDERS' EQUITY;
INTEREST RATES AND INTEREST DIFFERENTIAL
(in thousands of dollars)

| | Three Months Ended March 31, | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2007 | | | | 2006 | | | |
| | Average Balance | Interest Income | Yield (1) | | Average Balance | Interest Income | Yield (1) | |
| ASSETS | | | | | | | | |
| Earning assets: | | | | | | | | |
| Loans: | | | | | | | | |
| Taxable (2)(3) | $ 1,349,219 | $ 24,720 | 7.43 | % | $ 1,200,724 | $ 20,674 | 6.98 | % |
| Tax exempt (1) | 4,159 | 58 | 5.66 | | 5,125 | 71 | 5.65 | |
| Investments: (1) | | | | | | | | |
| Available for sale | 295,706 | 3,544 | 4.86 | | 291,636 | 3,452 | 4.80 | |
| Short-term investments | 15,092 | 199 | 5.35 | | 3,321 | 37 | 4.52 | |
| Interest bearing deposits | 762 | 9 | 4.79 | | 3,575 | 36 | 4.08 | |
| Total earning assets | 1,664,938 | 28,530 | 6.95 | % | 1,504,381 | 24,270 | 6.54 | % |
| Nonearning assets: | | | | | | | | |
| Cash and due from banks | 43,469 | 0 | | | 56,499 | 0 | | |
| Premises and equipment | 25,400 | 0 | | | 24,498 | 0 | | |
| Other nonearning assets | 52,300 | 0 | | | 48,234 | 0 | | |
| Less allowance for loan losses | (14,556) | 0 | | | (12,942) | 0 | | |
| Total assets | $ 1,771,551 | $ 28,530 | | | $ 1,620,670 | $ 24,270 | | |

(1) Tax exempt income was converted to a fully taxable equivalent basis at a 35 percent tax rate for 2007 and 2006. The tax equivalent rate for tax exempt loans and tax exempt securities acquired after January 1, 1983 included the TEFRA adjustment applicable to nondeductible interest expenses.

(2) Loan fees, which are immaterial in relation to total taxable loan interest income for the three months ended March 31, 2007 and 2006, are included as taxable loan interest income.

(3) Nonaccrual loans are included in the average balance of taxable loans.

DISTRIBUTION OF ASSETS, LIABILITIES AND STOCKHOLDERS' EQUITY;
INTEREST RATES AND INTEREST DIFFERENTIAL (Cont.)
(in thousands of dollars)

| | Three Months Ended March 31, | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2007 | | | | 2006 | | | |
| | Average Balance | Interest Expense | Yield | | Average Balance | Interest Expense | Yield | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | | | | | |
| Interest bearing liabilities: | | | | | | | | |
| Savings deposits | $ 66,196 | $ 34 | 0.21 | % | $ 67,885 | $ 35 | 0.21 | % |
| Interest bearing checking accounts | 370,242 | 2,996 | 3.28 | | 349,310 | 2,095 | 2.43 | |
| Time deposits: | | | | | | | | |
| In denominations under $100,000 | 277,477 | 3,238 | 4.73 | | 247,814 | 2,261 | 3.70 | |
| In denominations over $100,000 | 523,627 | 6,830 | 5.29 | | 393,225 | 4,333 | 4.47 | |
| Miscellaneous short-term borrowings | 139,887 | 1,430 | 4.15 | | 185,922 | 1,802 | 3.93 | |
| Long-term borrowings | 30,972 | 632 | 8.28 | | 30,973 | 587 | 7.69 | |
| Total interest bearing liabilities | 1,408,401 | 15,160 | 4.37 | % | 1,275,129 | 11,113 | 3.53 | % |
| Noninterest bearing liabilities and stockholders' equity: | | | | | | | | |
| Demand deposits | 216,541 | 0 | | | 216,855 | 0 | | |
| Other liabilities | 14,702 | 0 | | | 12,680 | 0 | | |
| Stockholders' equity | 131,907 | 0 | | | 116,006 | 0 | | |
| Total liabilities and stockholders' equity | $ 1,771,551 | $ 15,160 | | | $ 1,620,670 | $ 11,113 | | |
| Net interest differential - yield on average daily earning assets | | $ 13,370 | 3.25 | % | | $ 13,157 | 3.54 | % |

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**Provision for Loan Losses**

Based on management s review of the adequacy of the allowance for loan losses, provisions for losses on loans of $641,000 were recorded during the three-month period ended March 31, 2007, versus provisions of $453,000 recorded during the same period of 2006. Factors impacting the provision included the amount and status of classified credits, the level of charge-offs, management s overall view on current credit quality, the amount and status of impaired loans and the amount and status of past due accruing loans (90 days or more), as discussed in more detail below in the analysis relating to the Company s financial condition.

**Noninterest Income**

Noninterest income categories for the three-month periods ended March 31, 2007 and 2006 are shown in the following table:

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2007 | 2006 | Percent Change | |
| Wealth advisory and investment brokerage fees | $ 932 | $ 905 | 3.0 | % |
| Service charges on deposit accounts | 1,632 | 1,673 | (2.5) | |
| Loan, insurance and service fees | 581 | 573 | 1.4 | |
| Merchant card fee income | 622 | 580 | 7.2 | |
| Other income | 493 | 513 | (3.9) | |
| Net gains on sales of real estate mortgage loans held for sale | 165 | 152 | 8.6 | |
| Net securities gains (losses) | 36 | 2 | 1,700.0 | |
| Total noninterest income | $ 4,461 | $ 4,398 | 1.4 | % |

Noninterest income increased $63,000, or 1.4%, for the three-month period ended March 31, 2007, versus the same period in 2006. Wealth advisory and brokerage income increased by $27,000 in the three-month period ended March 31, 2007, primarily due to an increase in wealth advisory fees. Merchant card fee income increased by $42,000 driven by higher volume activity in interchange and merchant fees. Partially offsetting these increases were decreases in service charges on deposit accounts. This decline was driven by decreases in account analysis service charges on commercial checking accounts.

**Noninterest Expense**

Noninterest expense categories for the three-month periods ended March 31, 2007 and 2006 are shown in the following table:

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2007 | 2006 | Percent Change | |
| Salaries and employee benefits | $ 5,855 | $ 5,489 | 6.7 | % |
| Net occupancy expense | 674 | 609 | 10.7 | |
| Equipment costs | 445 | 455 | (2.2) | |
| Data processing fees and supplies | 659 | 550 | 19.8 | |
| Credit card interchange | 389 | 358 | 8.7 | |
| Other expense | 2,106 | 2,289 | (8.0) | |
| Total noninterest expense | $10,128 | $ 9,750 | 3.9 | % |

Noninterest expense increased $378,000, or 3.9%, in the three-month period ended March 31, 2007 versus the same period of 2006. Driving this increase were salaries and employee benefits, which increased $366,000, in the three-month period ended March 31, 2007. The increases were due largely to staff additions, normal salary increases, increased incentive based compensation and higher health care costs. Net occupancy expense increased due to higher maintenance and repair costs associated with an unusually harsh winter. In addition, data processing fees and supplies increased due to higher software license and maintenance fees. Offsetting these increases were decreases in other expense due to reduced advertising expense.

**Income Tax Expense**

Income tax expense decreased $373,000, or 15.5%, for the first three months of 2007, compared to the same period in 2006. The combined state franchise tax expense and the federal income tax expense, as a percentage of income before income tax expense, decreased to 29.9% during the first three months of 2007 compared to 34.1% during the same period of 2006. The decrease was driven by the formation of a real estate investment trust during the fourth quarter of 2006, which provides the Company with an alternative vehicle for raising capital should the need arise. Additionally, the ownership structure of this real estate investment trust provides certain state income tax benefits which also lowered the Company s effective tax rate.

**CRITICAL ACCOUNTING POLICIES**

Certain of the Company s accounting policies are important to the portrayal of the Company s financial condition, since they require management to make difficult, complex or subjective judgments, some of which may relate to matters that are inherently uncertain. Estimates associated with these policies are susceptible to material changes as a result of changes in facts and circumstances. Some of the facts and circumstances which could affect these judgments include changes in interest rates, in the performance of the economy or in the financial condition of borrowers. Management believes that its critical accounting policies include determining

the allowance for loan losses and the valuation of mortgage servicing rights. The Company s critical accounting policies are discussed in detail in the Annual Report for the year ended December 31, 2006 (incorporated by reference as part of the Company s 10-K filing).

**FINANCIAL CONDITION**

Total assets of the Company were $1.818 billion as of March 31, 2007, a decrease of $18.4 million, or 1.0%, when compared to $1.837 billion as of December 31, 2006.

Total cash and cash equivalents decreased by $43.0 million, or 36.0%, to $76.7 million at March 31, 2007 from $119.7 million at December 31, 2006.

Total securities available-for-sale increased by $2.1 million, or 0.7%, to $298.3 million at March 31, 2007 from $296.2 million at December 31, 2006. The increase was a result of a number of transactions in the securities portfolio. Securities purchases totaled $23.7 million and the fair market value of the securities portfolio increased by $941,000. A falling interest rate environment during the first quarter of 2007 drove the market value increase. Offsetting these increases were securities paydowns totaling $8.4 million, maturities, sales and calls of securities totaling $13.9 million and the amortization of premiums, net of the accretion of discounts totaling $239,000. The investment portfolio is managed to limit the Company s exposure to risk by containing mostly collateralized mortgage obligations and other securities which are either directly or indirectly backed by the federal government or a local municipal government.

Real estate mortgage loans held-for-sale decreased by $1.1 million, or 49.2%, to $1.1 million at March 31, 2007 from $2.2 million at December 31, 2006. The balance of this asset category is subject to a high degree of variability depending on, among other things, recent mortgage loan rates and the timing of loan sales into the secondary market. During the three months ended March 31, 2007, $11.4 million in real estate mortgages were originated for sale and $12.5 million in mortgages were sold.

Total loans, excluding real estate mortgage loans held-for-sale, increased by $24.1 million, or 1.8%, to $1.378 billion at March 31, 2007 from $1.354 billion at December 31, 2006. The mix of loan types within the Company s portfolio consisted of 81% commercial and industrial and agri-business, 8% real estate and 11% consumer loans at March 31, 2007 compared to 80% commercial and industrial and agri-business, 8% real estate and 12% consumer at December 31, 2006.

The Company has a relatively high percentage of commercial and commercial real estate loans, most of which are extended to small or medium-sized businesses. Commercial loans represent higher dollar loans to fewer customers and this concentration may lead to a higher credit risk than other types of loans. Pricing is adjusted to manage the higher credit risk associated with these types of loans. The majority of fixed rate mortgage loans, which represent increased interest rate risk, are sold in the secondary market, as well as some variable rate mortgage loans. The remainder of the variable rate mortgage loans and a small number of fixed rate mortgage loans are retained.

The regulations of the Federal Deposit Insurance Corporation require insured institutions to classify their own assets on a regular basis. The regulations provide for three categories of classified loans substandard, doubtful and loss. The regulations also contain a special mention category. Special mention is

defined as loans that do not currently expose an insured institution to a sufficient degree of risk to warrant classification, but do possess credit deficiencies or potential weaknesses deserving management s close attention. Assets classified as substandard or doubtful require the institution to establish specific allowances for loan losses. If an asset or portion thereof is classified as loss, the insured institution must either establish specified allowances for loan losses in the amount of 100% of the portion of the asset classified loss, or charge off such amount. At March 31, 2007, on the basis of management s review of the loan portfolio, the Company had loans totaling $69.0 million on the classified loan list versus $69.7 million on December 31, 2006. As of March 31, 2007, the Company had $32.9 million of assets classified special mention, $35.8 million classified as substandard, $280,000 classified as doubtful and $0 classified as loss as compared to $26.9 million, $42.6 million, $100,000 and $0 at December 31, 2006.

Loans are charged against the allowance for loan losses when management believes that the uncollectability of the principal is confirmed. Subsequent recoveries, if any, are credited to the allowance. The allowance is an amount that management believes will be adequate to absorb probable incurred credit losses relating to specifically identified loans based on an evaluation, as well as other probable incurred losses inherent in the loan portfolio. The evaluations take into consideration such factors as changes in the nature and volume of the loan portfolio, overall portfolio quality, review of specific problem loans and current economic conditions that may affect the borrower s ability to repay. Management also considers trends in adversely classified loans based upon a monthly review of those credits. An appropriate level of general allowance is determined after considering the following factors: application of historical loss percentages, emerging market risk, commercial loan focus and large credit concentrations, new industry lending activity and current economic conditions.

The Company discusses this methodology with regulatory authorities to ensure compliance. Allowance estimates are considered a prudent measurement of the risk in the Company s loan portfolio and are applied to individual loans based on loan type. In accordance with FASB Statements 5 and 114, the allowance is provided for losses that have been incurred as of the balance sheet date and is based on past events and current economic conditions, and does not include the effects of expected losses on specific loans or groups of loans that are related to future events or expected changes in economic conditions.

The allowance for loan losses increased $295,000 from $14.5 million December 31, 2006 to $14.8 million at March 31, 2007. Pooled loan allocations increased $117,000 from $4.2 million at December 31, 2006 to $4.3 million at March 31, 2007, which was primarily a result of an increase in pooled loan balances of $24.4 million year to date. Specific loan allocations increased $259,000 from $9.7 million at December 31, 2006 to $9.9 million at March 31, 2007. This increase was primarily from increases in the specific allocations for two commercial credits. The unallocated component of the allowance for loan losses decreased $82,000 from $638,000 at December 31, 2006 to $556,000 at March 31, 2007. Management believes the allowance for loan losses is at a level commensurate with the overall risk exposure of the loan portfolio. However, if economic conditions would become unfavorable certain borrowers may experience difficulty and the level of nonperforming loans, charge-offs and delinquencies could rise and require further increases in the provision for loan losses.

Total impaired loans decreased by $107,000 to $13.2 million at March 31, 2007 from $13.3 million at December 31, 2006. The decrease in the impaired loans category resulted primarily from paydowns in several commercial credits. The impaired loan total included $195,000 in accruing loans at March 31, 2007. A loan is

impaired when full payment under the original loan terms is not expected. Impairment is evaluated in total for smaller-balance loans of similar nature such as residential mortgage, and consumer loans, and on an individual loan basis for other loans. If a loan is impaired, a portion of the allowance may be allocated so that the loan is reported, net, at the present value of estimated future cash flows using the loan s existing rate or at the fair value of collateral if repayment is expected solely from the collateral. The following table summarizes nonperforming assets at March 31, 2007 and December 31, 2006.

| | March 31, 2007 (in thousands) | December 31, 2006 |
|---|---|---|
| NONPERFORMING ASSETS: | | |
| Nonaccrual loans | $ 13,438 | $ 13,820 |
| Loans past due over 90 days and accruing | 334 | 299 |
| Total nonperforming loans | 13,772 | 14,119 |
| Other real estate | 71 | 71 |
| Repossessions | 35 | 35 |
| Total nonperforming assets | $ 13,878 | $ 14,225 |
| Total impaired loans | $ 13,226 | $ 13,333 |
| Nonperforming loans to total loans | 1.00% | 1.04% |
| Nonperforming assets to total assets | 0.76% | 0.77% |

Total deposits increased by $22.2 million, or 1.5%, to $1.498 billion at March 31, 2007 from $1.476 billion at December 31, 2006. The increase resulted from increases of $103.1 million in certificates of deposit, $5.5 million in savings accounts and $5.3 million in Investors Money Market accounts. Offsetting these increases were declines of $87.1 million in money market transaction accounts, $4.5 million in demand deposit accounts and $42,000 in money market accounts. Total short-term borrowings decreased by $48.0 million, or 25.6%, to $139.5 million at March 31, 2007 from $187.5 million at December 31, 2006. The decrease resulted primarily from decreases of $80.0 million in other borrowings, primarily short-term advances from the Federal Home Loan Bank of Indianapolis partially offset by increases of $21.5 million in federal funds purchased and $11.3 million in securities sold under agreements to repurchase.

Total stockholders equity increased by $4.8 million, or 3.7%, to $134.9 million at March 31, 2007 from $130.2 million at December 31, 2006. Net income of $4.8 million, plus the increase in the accumulated other comprehensive income of $600,000, minus dividends of $1.5 million, plus $870,000 for stock issued through options exercised (including tax benefit), minus $113,000 for the cost of treasury stock purchased plus $45,000 in stock option expense, comprised most of this increase.

The FDIC s risk based capital regulations require that all insured banking organizations maintain an 8.0% total risk based capital ratio. The FDIC has also established definitions of well capitalized as a 5.0% Tier I leverage capital ratio, a 6.0% Tier I risk based capital ratio and a 10.0% total risk based capital ratio. All of the Company s ratios continue to be above well capitalized levels. As of March 31, 2007, the Company s

Tier 1 leverage capital ratio, Tier 1 risk based capital ratio and total risk based capital ratio were 9.1%, 11.0% and 12.0%, respectively.

**FORWARD-LOOKING STATEMENTS**

This document (including information incorporated by reference) contains, and future oral and written statements of the Company and its management may contain, forward-looking statements, within the meaning of such term in the Private Securities Litigation Reform Act of 1995, with respect to the financial condition, results of operations, plans, objectives, future performance and business of the Company. Forward-looking statements, which may be based upon beliefs, expectations and assumptions of the Company s management and on information currently available to management, are generally identifiable by the use of words such as believe, expect, anticipate, plan, intend, estimate, will, would, could, should or other similar expressions. Additionally, all statements in this document, including forward-looking statements, speak only as of the date they are made, and the Company undertakes no obligation to update any statement in light of new information or future events.

The Company s ability to predict results or the actual effect of future plans or strategies is inherently uncertain. The factors, which could have a material adverse effect on the operations and future prospects of the Company and its subsidiaries are detailed in the Risk Factors section included under Item 1a. of Part I of our Form 10-K. In addition to the risk factors described in that section, there are other factors that may impact any public company, including ours, which could have a material adverse effect on the operations and future prospects of the Company and its subsidiaries. These risks and uncertainties should be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

**ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Interest rate risk represents the Company s primary market risk exposure. The Company does not have a material exposure to foreign currency exchange risk, does not have any material amount of derivative financial instruments and does not maintain a trading portfolio. The board of directors annually reviews and approves the policy used to manage interest rate risk. The policy was last reviewed and approved in May 2006. The policy sets guidelines for balance sheet structure, which are designed to protect the Company from the impact that interest rate changes could have on net income, but does not necessarily indicate the effect on future net interest income. The Company, through its Asset/Liability Committee, manages interest rate risk by monitoring the computer simulated earnings impact of various rate scenarios and general market conditions. The Company then modifies its long-term risk parameters by attempting to generate the type of loans, investments, and deposits that currently fit the Company s needs, as determined by the Asset/Liability Committee. This computer simulation analysis measures the net interest income impact of various interest rate scenario changes during the next 12 months. If the change in net interest income is less than 3% of primary capital, the balance sheet structure is considered to be within acceptable risk levels. At March 31, 2007, the Company s potential pretax exposure was within the Company s policy limit, and not significantly different from December 31, 2006.

**ITEM 4 CONTROLS AND PROCEDURES**

As required by Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, management has evaluated, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, the

effectiveness of the Company s disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, the Company s Chief Executive Officer and Chief Financial Officer concluded the Company s disclosure controls and procedures (as defined in Securities Exchange Act Rules 13a-15(e) and 15d-15(e)) were effective as of March 31, 2007. Disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. These disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to management, including the Company s Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the quarter ended March 31, 2007, there were no changes to the Company s internal control over financial reporting that has materially affected or is reasonably likely to materially affect its control over financial reporting.

**LAKELAND FINANCIAL CORPORATION**

**FORM 10-Q**

**March 31, 2007**

**Part II - Other Information**

Item 1. Legal proceedings

There are no material pending legal proceedings to which the Company or its subsidiaries is a party other than ordinary routine litigation incidental to their respective businesses.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in Item 1A. to Part I of the Company s 2006 Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table provides information as of March 31, 2007 with respect to shares of common stock repurchased by the Company during the quarter then ended:

Issuer Purchases of Equity Securities(a)

| Period | Total Number of Shares Purchased | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Appropriate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| January 1-31 | 4,081 | $ 25.06 | 0 | $ 0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| February 1-28 | 466 | 24.45 | | 0 | 0 | |
| March 1-31 | 0 | 0 | | 0 | 0 | |
| Total | 4,547 | $ | 25.00 | 0 | $ | 0 |

(a) The shares purchased during the periods were credited to the deferred share accounts of seven non-employee directors under the Company s director s deferred compensation plan.

Item 3. Defaults Upon Senior Securities

None

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Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Other Information

None

Item 6. Exhibits

31.1 Certification of Chief Executive Officer Pursuant to Rule 13a-15(e)/15d-15(e) and 13(a)-15(f)/15d-15(f)

31.2 Certification of Chief Financial Officer Pursuant to Rule 13a-15(e)/15d-15(e) and 13(a)-15(f)/15d-15(f)

32.1 Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**LAKELAND FINANCIAL CORPORATION**

**FORM 10-Q**

**March 31, 2007**

**Part II - Other Information**

**Signatures**

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

LAKELAND FINANCIAL CORPORATION

(Registrant)

| | |
|---|---|
| Date: May 1, 2007 | /s/ Michael L. Kubacki<br>Michael L. Kubacki President and Chief Executive Officer |
| Date: May 1, 2007 | /s/ David M. Findlay<br>David M. Findlay Executive Vice President and Chief Financial Officer |
| Date: May 1, 2007 | /s/ Teresa A. Bartman<br>Teresa A. Bartman Vice President and Controller |

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