OLD NATIONAL BANCORP /IN/ Form S-4 December 05, 2013 <u>Table of Contents</u>

As filed with the Securities and Exchange Commission on December 5, 2013

**Registration No.** 

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM S-4

**REGISTRATION STATEMENT** 

UNDER

THE SECURITIES ACT OF 1933

# **Old National Bancorp**

(Exact name of registrant as specified in its charter)

Indiana (State or other jurisdiction of incorporation or organization) 6021 (Primary standard industrial classification code number) **35-1539838** (I.R.S. Employer Identification No.)

#### ONE MAIN STREET, EVANSVILLE, INDIANA 47708, (812) 464-1294

(Address, including zip code and telephone number, including area code, of principal executive offices)

Jeffrey L. Knight, Esq.

**Executive Vice President**,

**Corporate Secretary and Chief Legal Counsel** 

**Old National Bancorp** 

**One Main Street** 

Evansville, Indiana 47708

(812) 464-1294

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Timothy M. Harden, Esq. Michael J. Messaglia, Esq. Krieg DeVault LLP One Indiana Square, Suite 2800 Indianapolis, Indiana 46204 (317) 636-4341 Robert S. Walters, Esq. Samuel J. Talarico, Jr., Esq. Barrett & McNagny LLP 215 East Berry Street Fort Wayne, Indiana 46802 (260) 423-9551

Approximate date of commencement of proposed sale of the securities to the public: As soon as practicable after this Registration Statement becomes effective and upon the effective time of the merger of Tower Financial Corporation with and into Registrant pursuant to the Agreement and Plan of Merger described in the proxy statement/prospectus included in Part I of this Registration Statement.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

(Check one): Large accelerated filer x Non-accelerated filer o (Do not check if a smaller reporting company) Accelerated filer o Smaller reporting company o

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer) o Exchange Act Rule 14d-1(d) (Cross-Border Third Party Tender Offer) o

#### CALCULATION OF REGISTRATION FEE

		Р	roposed Maximum	Proposed Maximum	
Title of Each Class of Securities	Amount to be		Offering Price	Aggregate	Amount of
to be Registered	Registered(1)		Per Share(2)	Offering Price(2)	Registration Fee
Common Stock, no par value	5,652,553	\$	24.96	\$ 117,573,106.56	\$ 15,143.42

(1) This registration statement covers the maximum number of shares of common stock of the Registrant which are expected to be issued in connection with the merger based upon applying an exchange ratio of 1.20 to the number of shares of Tower Financial Corporation (TFC) common stock outstanding or reserved for issuance upon the exercise of outstanding stock options.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) and Rule 457(f), based on the average of the high and low prices of a share of Tower Financial Corporation s common stock on November 29, 2013, multiplied by 4,710,461 shares of common stock of TFC that may be received by the Registrant and/or cancelled upon consummation of the merger.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

#### THE INFORMATION IN THIS PROXY STATEMENT-PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. WE MAY NOT ISSUE THESE SECURITIES UNTIL THE REGISTRATION STATEMENT IS EFFECTIVE. THIS PROXY STATEMENT-PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

#### PRELIMINARY PROXY STATEMENT/PROSPECTUS

DATED DECEMBER 5, 2013, SUBJECT TO COMPLETION

[TFC LOGO]

#### PROXY STATEMENT FOR THE SPECIAL MEETING OF

#### TOWER FINANCIAL CORPORATION SHAREHOLDERS

and

#### PROSPECTUS OF

#### OLD NATIONAL BANCORP

The Boards of Directors of Tower Financial Corporation (TFC) and Old National Bancorp (Old National) have approved an agreement to merge (the Merger) TFC with and into Old National (the Merger Agreement). If the Merger is approved by the shareholders of TFC and all other closing conditions are satisfied, each shareholder of TFC shall receive \$6.75 in cash and 1.20 shares of Old National common stock for each share of TFC common stock owned before the Merger, subject to certain adjustments as described in the Merger Agreement. Each TFC shall exceive shareholder will also receive cash in lieu of any fractional shares of Old National common stock that such shareholder would otherwise receive in the Merger, based on the market value of Old National common stock determined shortly before the closing of the Merger. The board of directors of TFC believes that the Merger is in the best interests of TFC and its shareholders.

The Merger is conditioned upon, among other things, the approval of TFC s shareholders. This document is a proxy statement that TFC is using to solicit proxies for use at its special meeting of shareholders to be held on February 7, 2014. At the meeting, TFC s shareholders will be asked (i) to approve the Merger Agreement and the Merger, (ii) to approve, in a non-binding advisory vote, the compensation that may or will be payable to TFC s named executive officers in connection with the Merger, (iii) to adjourn the meeting if necessary to solicit additional proxies, and (iv) to transact such other business as may properly be brought before the meeting or any adjournment or postponement thereof.

This document is also a prospectus relating to Old National s issuance of up to 5,652,553 shares of Old National common stock in connection with the Merger.

Old National common stock is traded on the NASDAQ Global Market under the trading symbol ONB. On September 9, 2013, the date of execution of the Merger Agreement, the closing price of a share of Old National common stock was \$13.77. On November 29, 2013, the closing price of a share of Old National common stock was \$15.55.

TFC common stock is traded on the NASDAQ Global Market under the trading symbol TOFC. On September 9, 2013, the date of execution of the Merger Agreement, the closing price of a share of TFC common stock was \$15.66. On November 29, 2013, the closing price of a share of TFC common stock was \$24.96.

# For a discussion of certain risk factors relating to the Merger Agreement, see the section captioned Risk Factors beginning on page 20.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities to be issued under this proxy statement/prospectus or determined if this proxy statement/prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The securities to be issued in connection with the Merger are not savings or deposit accounts or other obligations of any bank or nonbank subsidiary of any of the parties, and they are not insured by the Federal Deposit Insurance Corporation, the Deposit Insurance Fund or any other governmental agency.

This proxy statement/prospectus is dated [ ], 2013, and it

is first being mailed to TFC shareholders on or about [], 2013.



#### **AVAILABLE INFORMATION**

As permitted by Securities and Exchange Commission (SEC) rules, this document incorporates certain important business and financial information about Old National from other documents that are not included in or delivered with this document. These documents are available to you without charge upon your written or oral request. Your requests for these documents should be directed to the following:

Old National Bancorp

One Main Street

P.O. Box 718

Evansville, Indiana 47705

Attn: Jeffrey L. Knight, Executive Vice President,

Corporate Secretary and Chief Legal Counsel

(812) 464-1363

In order to ensure timely delivery of these documents, you should make your request by [ ], 2013, to receive them before the special meeting.

You can also obtain documents incorporated by reference in this document through the SEC s website at www.sec.gov. See Where You Can Find More Information.

#### TOWER FINANCIAL CORPORATION

#### 116 East Berry Street

Fort Wayne, Indiana 46802

#### (260) 427 7000

#### NOTICE OF SPECIAL MEETING OF SHAREHOLDERS

#### TO BE HELD ON FEBRUARY 7, 2014

To the Shareholders of Tower Financial Corporation:

We will hold a special meeting of the shareholders of Tower Financial Corporation (TFC) on February 7, 2014, at 9:30 a.m., Eastern Time, at the Landmark Centre, 6222 Ellison Road, Fort Wayne, Indiana 46802, to consider and vote upon:

1. *Merger Proposal.* To approve the Agreement and Plan of Merger dated September 9, 2013 (the Merger Agreement ), by and between Old National Bancorp (Old National ) and TFC, pursuant to which TFC will merge with and into Old National (the Merger ). Simultaneous with the consummation of the Merger, Tower Bank & Trust Company will merge with Old National Bank, the wholly-owned banking subsidiary of Old National. In connection with the Merger, you will receive in exchange for each of your shares of TFC common stock:

• 1.20 shares of Old National common stock (the Exchange Ratio ), subject to adjustment as provided in the Merger Agreement;

• \$6.75 in cash, without interest; and

• in lieu of any fractional share of Old National common stock, an amount in cash equal to such fraction multiplied by the average per share closing price of a share of Old National common stock as quoted on the NASDAQ during the ten trading days preceding the fifth calendar day preceding the effective time of the Merger.

2. *Shareholder Advisory (Non-Binding) Vote on Merger-Related Compensation.* Consideration and approval, on a non-binding advisory basis, of the compensation that may or will become payable to the named executive officers of TFC in connection with the Merger.

3. *Adjournment.* To approve a proposal to adjourn the special meeting, if necessary, to solicit additional proxies in the event there are not sufficient votes present at the special meeting in person or by proxy to approve the Merger.

4. *Other Matters.* To vote upon such other matters as may properly come before the meeting or any adjournment thereof. The board of directors is not aware of any such other matters.

The enclosed proxy statement/prospectus describes the Merger Agreement and the proposed Merger in detail and includes, as Annex A, the complete text of the Merger Agreement. We urge you to read these materials for a description of the Merger Agreement and the proposed Merger. In particular, you should carefully read the section captioned Risk Factors beginning on page [] of the enclosed proxy statement/prospectus for a discussion of certain risk factors relating to the Merger Agreement and the Merger.

The board of directors of TFC recommends that TFC shareholders vote (1) FOR adoption of the Merger Agreement and the Merger, (2) FOR approval of the non-binding advisory resolution regarding the Merger-related compensation payable to our named executive officers, and (3) FOR adjournment of the special meeting, if necessary.

The board of directors of TFC fixed the close of business on November 29, 2013, as the record date for determining the shareholders entitled to notice of, and to vote at, the special meeting and any adjournments or postponements of the special meeting.

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**YOUR VOTE IS VERY IMPORTANT**. The Merger Agreement must be adopted by the affirmative vote of holders of a majority of the issued and outstanding shares of TFC common stock in order for the proposed Merger to be consummated. If you do not return your proxy card or do not vote in person at the special meeting, the effect will be a vote against the proposed Merger. Whether or not you plan to attend the special meeting in person, we urge you to date, sign and return promptly the enclosed proxy card in the accompanying envelope. You may revoke your proxy at any time before the special meeting by sending a written notice of revocation, submitting a new proxy card or by attending the special meeting and voting in person.

By Order of the Board of Directors

/s/ Michael D. Cahill Michael D. Cahill President and Chief Executive Officer

[], 2013

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#### QUESTIONS AND ANSWERS ABOUT THE MERGER AND THE SPECIAL MEETING

#### Q: What am I voting on?

A: Old National is proposing to acquire TFC. You are being asked to vote to approve the Merger Agreement and the Merger. In the Merger, TFC will merge into Old National. Old National would be the surviving entity in the Merger, and TFC would no longer be a separate company.

Additionally, you are being asked to vote to approve (i) on a non-binding advisory basis, the compensation payable to the named executive officers of TFC in connection with the Merger, and (ii) a proposal to adjourn the special meeting, if necessary, to solicit additional proxies if enough votes have not been cast to approve the Merger Agreement at the time of the special meeting.

Q: What will I receive in the Merger?

A: If the Merger is completed, each share of TFC common stock will be converted into the right to receive 1.20 shares of Old National common stock (the Exchange Ratio ), subject to adjustment as provided below, and \$6.75 in cash (collectively, the Merger Consideration ). The Exchange Ratio is subject to adjustment as follows:

• if, as of end of the month prior to the effective time, the TFC shareholders equity (computed in accordance with the terms of the Merger Agreement) is less than \$61,117,844, the Exchange Ratio will be decreased as provided in the Merger Agreement; and

• if the average closing price of a share of Old National common stock (computed in accordance with the terms of the Merger Agreement) decreases by more than 20% in relation to a prescribed bank index, TFC will have the right to terminate the Merger Agreement unless Old National elects to increase the Exchange Ratio.

In lieu of any fractional shares of Old National common stock, Old National will distribute an amount in cash equal to such fraction multiplied by the average per share closing price of a share of Old National common stock as quoted on the NASDAQ Global Market during the ten trading days preceding the fifth calendar day preceding the effective time of the Merger.

#### Q: What risks should I consider before I vote on the Merger Agreement?

A: You should review Risk Factors beginning on page [].

#### Q: Will Old National shareholders receive any shares or cash as a result of the Merger?

A: No. Old National shareholders will continue to own the same number of Old National shares they owned before the effective time of the Merger.

#### **Q:** When is the Merger expected to be completed?

A: We are working to complete the Merger as quickly as possible. We first must obtain the necessary regulatory approvals and the approval of the TFC shareholders at the special meeting being held for its shareholders to, among other matters, vote on the Merger. We currently expect to complete the Merger during the first quarter of 2014.

#### Q: What are the tax consequences of the Merger to me?

A: We have structured the Merger so that Old National, TFC, and their respective shareholders will not recognize any gain or loss for federal income tax purposes on the exchange of TFC shares for Old National shares in the Merger. Taxable income will result, however, to the extent a TFC shareholder receives cash (including cash received in lieu of fractional shares of Old National common stock) and the cash received exceeds the shareholder s adjusted basis in the surrendered stock. At the closing, TFC is to receive an opinion confirming these tax consequences. See Material Federal Income Tax Consequences beginning on page [].

Your tax consequences will depend on your personal situation. You should consult your tax advisor for a full understanding of the tax consequences of the Merger to you.

#### Q: What happens if I do not return a proxy card or otherwise vote?

A: Because the required vote of TFC shareholders on the Merger is based upon the number of outstanding shares of TFC common stock entitled to vote rather than upon the number of shares actually voted, abstentions from voting and broker non-votes will have the same practical effect as a vote AGAINST approval and adoption of the Merger Agreement. If you return a properly signed proxy card but do not indicate how you want to vote, your proxy will be counted as a vote FOR approval and adoption of the Merger Agreement.

The advisory votes on the Merger-related compensation and the vote to adjourn the meeting, if necessary, each require more votes to be cast in favor of these proposals than against. Abstentions and broker non-votes will have no effect on these proposals.

# Q: Why am I being asked to cast an advisory (non-binding) vote to approve the compensation payable to certain TFC officers in connection with the Merger?

A: The Securities and Exchange Commission, in accordance with the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, requires TFC to seek an advisory (non-binding) vote with respect to certain payments that will or may be made to TFC s named executive officers in connection with the Merger.

#### **Q:** What will happen if TFC shareholders do not approve such compensation at the special meeting?

A: Approval of the compensation payable in connection with the Merger is not a condition to completion of the Merger. The vote with respect to such compensation is an advisory vote and will not be binding on TFC (or the combined company that results from the Merger) regardless of whether the Merger Agreement is approved. Accordingly, as the compensation to be paid to the TFC executives in connection with the Merger is contractual, such compensation will or may be payable if the Merger is completed regardless of the outcome of the advisory vote.

#### Q: Will I have dissenters rights?

A: No. Because TFC s common stock is traded on a national exchange, shareholders are not entitled to dissenters rights under the Indiana Business Corporation Law.

Q: What do I need to do now?

A: After reading this proxy statement/prospectus, you may vote in one of four ways: (1) by mail (by completing and signing the proxy card that accompanies this prospectus/proxy statement); (2) by telephone; (3) by using the Internet; and (4) in person (by either delivering the completed proxy card or by casting a ballot if attending the special meeting). In the event that you choose not to exercise your vote by telephone, internet or in person, you should mail your signed proxy card in the accompanying pre-addressed, postage-paid envelope as soon as possible so that your shares can be voted at the February 7, 2014, TFC special meeting.

The telephone and Internet voting procedures have been set up for your convenience and have been designed to authenticate your identity, to allow you to give voting instructions, and to confirm that those instructions have been properly recorded. If you would like to vote by telephone or by using the Internet, please refer to the specific instructions on the proxy card. The deadline for voting by telephone or via the Internet is 11:59 p.m. Eastern Time on February 6, 2014.

#### Q: If my shares are held in street name by my broker, will my broker vote my shares for me?

A: Yes. Your broker will vote your shares on the Merger Agreement, but only if you provide instructions on how to vote. You should contact your broker and ask what directions your broker will need from you. If you do not provide instructions to your broker on how to vote on the Merger Agreement, your broker will not be able to vote your shares, and this will have the effect of voting against the Merger Agreement.

Similarly, your broker will vote your shares on the shareholder advisory (non-binding) vote on the Merger-related compensation, and the proposal to adjourn the meeting, if necessary, but only if you provide instructions on how to vote. If you do not submit voting instructions to your broker, your shares will not be counted in determining the outcome of those proposals.

#### Q: How do I vote shares held in TFC s 401(k) Plans?

A: TFC maintains 401(k) Plan which owns approximately 126,437 shares of TFC s common stock. Employees of TFC and its subsidiaries may participate in the plans. Each participant instructs the trustee how to vote the shares of TFC common stock allocated to his or her account under the Plan. Principal Trust Company is the trustee of the Plan. A participant may vote in one of four ways: (1) by mail (by completing and signing the proxy card that accompanies this prospectus/proxy statement); (2) by telephone; (3) by using the Internet; and (4) in person (by either delivering the completed proxy card or by casting a ballot if attending the special meeting).

If a participant properly executes the voting instruction card distributed by the trustee, the trustee will vote such participant s shares in accordance with the shareholder s instructions. Where properly executed voting instruction cards are returned to the trustee with no specific instruction as to how to vote at the special meeting, the trustee will vote the shares FOR the proposal to approve the Merger Agreement and the Merger, FOR the approval of the Merger-related compensation that is based on or otherwise relates to the Merger, and FOR the proposal to adjourn the special meeting, if necessary, to solicit additional proxies in the event there are not sufficient votes present at the special meeting in person or by proxy to approve the Merger. The trustee will vote the shares of TFC common stock held in the Plan but not allocated to any participant s account and shares as to which no voting instruction cards are received in the same proportion as the allocated shares in the Plan are voted with respect to the items being presented to a shareholder vote.

The telephone and Internet voting procedures have been set up for participant convenience and have been designed to authenticate each participant s identity, to allow such participants to give voting instructions, and to confirm that those instructions have been properly recorded. If a participant would like to vote by telephone or by using the Internet, please refer to the specific instructions on the proxy card. The deadline for voting by telephone or via the Internet is 11:59 p.m. Eastern Time on February 6, 2014.

#### Q: Can I change my vote after I have mailed my signed proxy card?

A: Yes. You can change your vote at any time before your proxy is voted at the special meeting. You can do this in one of three ways. First, you can send a written notice stating that you revoke your proxy. Second, you can complete and submit a new proxy card, dated at a date later than the first proxy card. Third, you can attend the special meeting and vote in person. Your attendance at the special meeting will not, however, by itself revoke your proxy. If you hold your shares in street name and have instructed your broker how to vote your shares, you must follow directions received from your broker to change those instructions.

#### Q: What constitutes a quorum?

A: The holders of over 50% of the outstanding shares of common stock as of the record date must be present in person or by proxy at the special meeting to constitute a quorum. In determining whether a quorum is present, shareholders who abstain, cast broker non-votes, or are otherwise present at the meeting will be deemed present at the special meeting. Once a share is represented for any purpose at a meeting, it is deemed present for quorum purposes for the remainder of the meeting.

#### Q: Should I send in my stock certificates now?

A: No. As soon as practicable after the completion of the Merger, you will receive a letter of transmittal describing how you may exchange your shares for the Merger Consideration. At that time, you must send your completed letter of transmittal to Old National in order to receive the Merger Consideration. You should not send your share certificate until you receive the letter of transmittal.

#### Q: Can I elect the form of payment that I prefer in the Merger?

A: No. The amount of cash and shares of Old National common stock to be issued in the Merger have been determined, subject to those adjustments set forth herein.

#### Q: Whom should I contact if I have other questions about the Merger Agreement or the Merger?

A: If you have more questions about the Merger Agreement or the Merger, you should contact:

Old National Bancorp One Main Street Evansville, Indiana 47708 (812) 464-1294 Attn: Jeffrey L. Knight

You may also contact:

Tower Financial Corporation 116 East Berry Street Fort Wayne, Indiana 46802 (260) 427-7000 Attn: Michael D. Cahill

#### SUMMARY

This summary highlights selected information in this proxy statement/prospectus and may not contain all of the information important to you. To understand the Merger more fully, you should read this entire document carefully, including the annexes and the documents referred to in this proxy statement/prospectus. A list of the documents incorporated by reference appears under the caption Where You Can Find More Information on page [].

The Companies (page [ ])

Old National Bancorp

**One Main Street** 

Evansville, Indiana 47708

(812) 464-1294

Old National Bancorp is a bank holding company, incorporated under Indiana law and headquartered in Evansville, Indiana. Old National is the largest financial services holding company headquartered in Indiana and, with \$9.6 billion in assets, ranks among the top 100 banking companies in the United States. Since its founding in Evansville in 1834, Old National has focused on community banking by building long-term, highly valued partnerships with clients in its primary footprint of Indiana, Illinois and Kentucky. In addition to providing extensive services in retail and commercial banking, wealth management, investments and brokerage, Old National also owns Old National Insurance which is one of the top 100 largest agencies in the U.S. and the 10th largest bank-owned agency. Old National s common stock is traded on the NASDAQ Global Market under the symbol ONB .

Tower Financial Corporation

116 East Berry Street

Fort Wayne, Indiana 46802

(260) 427 7000

Tower Financial Corporation, headquartered in Fort Wayne, Indiana, is an Indiana financial services holding company with one subsidiary: Tower Bank & Trust Company, a growing community bank that opened in February 1999. Tower Bank & Trust Company provides a wide variety of financial services to businesses and consumers through its six full-service financial centers in Fort Wayne and a seventh in Warsaw, Indiana. Tower Bank & Trust Company has a wholly-owned subsidiary, Tower Trust Company, which is a state-chartered wealth services firm doing business as Tower Private Advisors. TFC s common stock is traded on the NASDAQ Global Market under the symbol TOFC .

#### Special Meeting of Shareholders; Required Vote (page [ ])

The special meeting of TFC shareholders is scheduled to be held at the Landmark Centre, 6222 Ellison Road, Fort Wayne, Indiana 46802 at 9:30 a.m., Eastern Time, on February 7, 2014. At the TFC special meeting, you will be asked to vote to approve the Merger Agreement and the Merger of TFC into Old National contemplated by that agreement. You will also be asked to approve, on a non-binding advisory basis, certain compensation payable to certain TFC executive officers in connection with the Merger and a proposal to adjourn the special meeting to solicit additional proxies, if necessary. Only TFC shareholders of record as of the close of business on November 29, 2013, are entitled to notice of, and to vote at, the TFC special meeting and any adjournments or postponements of the TFC special meeting.

As of the record date, there were 4,675,526 shares of TFC common stock outstanding. The directors and executive officers of TFC (and their affiliates), as a group, owned with power to vote 1,085,237 shares of TFC common stock, representing approximately 23.2% of the outstanding shares of TFC common stock as of the record date.

Adoption of the Merger Agreement requires the affirmative vote of holders of a majority of the issued and outstanding shares of TFC common stock. Approval of the proposal to adjourn the special meeting to allow extra time to solicit proxies and the advisory votes on the Merger-related compensation each require more votes cast in favor of the proposal than are cast against it.

No approval by Old National shareholders is required.

The Merger and the Merger Agreement (pages [ ] and [ ])

Old National s acquisition of TFC is governed by the Merger Agreement. The Merger Agreement provides that, if all of the conditions are satisfied or waived, TFC will be merged with and into Old National, with Old National surviving. Simultaneous with the Merger, Tower Bank & Trust Company will be merged with and into Old National Bank, a wholly-

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owned subsidiary of Old National. We encourage you to read the Merger Agreement, which is included as Annex A to this proxy statement/prospectus and is incorporated by reference herein.

#### What TFC Shareholders Will Receive in the Merger (page [ ])

If the Merger is completed, each share of TFC common stock will be converted into the right to receive 1.20 shares of Old National common stock (the Exchange Ratio ), subject to the following adjustments, and \$6.75 in cash:

• if, as of end of the month prior to the effective time, the TFC shareholders equity (computed in accordance with the terms of the Merger Agreement) is less than \$61,117,844, the Exchange Ratio will be decreased as provided in the Merger Agreement; and

• if the average closing price of a share of Old National common stock (computed in accordance with the terms of the Merger Agreement) decreases by more than 20% in relation to a prescribed bank index, TFC will have the right to terminate the Merger Agreement unless Old National elects to increase the Exchange Ratio.

In lieu of any fractional shares of Old National common stock, Old National will distribute an amount in cash equal to such fraction multiplied by the average per share closing price of a share of Old National common stock as quoted on the NASDAQ during the ten trading days preceding the fifth calendar day preceding the effective time of the Merger.

#### Treatment of Options to Acquire Shares of TFC Common Stock (page [ ])

The Merger Agreement provides that each option to acquire shares of TFC common stock outstanding as of the effective date of the Merger will be converted into options to acquire shares of Old National common stock.

#### **Treatment of Deferred Stock Units**

The Merger Agreement also provides that Old National and TFC will take all requisite action so that, at the effective time of the Merger, each of the deferred stock units issued and still outstanding under TFC s 2006 Equity Incentive Plan (consisting of 5,133 units) will receive cash in the amount equal to the closing price of a share of TFC common stock on the trading day immediately preceding the closing of the Merger.

Recommendation of TFC Board of Directors (page [ ])

The TFC board of directors approved the Merger Agreement and the proposed Merger. The TFC board believes that the Merger Agreement, including the Merger contemplated by the Merger Agreement, is advisable and fair to, and in the best interests of, TFC and its shareholders, and therefore recommends that TFC shareholders vote FOR the proposal to approve the Merger Agreement and the Merger. In reaching its decision, the TFC board of directors considered a number of factors, which are described in the section captioned Proposal 1 The Merger TFC s Reasons for the Merger and Recommendation of the Board of Directors beginning on page []. Because of the wide variety of factors considered, the TFC board of directors did not believe it practicable, nor did it attempt, to quantify or otherwise assign relative weight to the specific factors it considered in reaching its decision.

The TFC Board also recommends that you vote FOR the approval of the Merger-related compensation that is based on or otherwise relates to the Merger and FOR the proposal to adjourn the special meeting, if necessary, to solicit additional proxies in the event there are not sufficient votes present at the special meeting in person or by proxy to approve the Merger.

No Dissenters Right(page [ ])

Dissenters rights are statutory rights that, if available under law, enable shareholders to dissent from an extraordinary transaction, such as a merger, and to demand that the corporation pay the fair value for their shares as determined by a court in a judicial proceeding instead of receiving the consideration offered to shareholders in connection with the extraordinary transaction. Dissenters rights are not available in all circumstances, and exceptions to these rights are provided in the Indiana Business Corporation Law. Because shares of TFC common stock are sold on a national exchange, holders of TFC common stock will not have dissenters rights in connection with the Merger.

Voting Agreements (page [ ])

As of the record date, the directors of TFC beneficially owned 1,043,072 shares of TFC common stock, including shares subject to options currently exercisable but not exercised. In connection with the execution of the Merger Agreement, the directors of TFC each executed a voting agreement pursuant to which they agreed to vote their shares, and to use

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reasonable efforts to cause all shares owned by such director jointly with another person or by such director s spouse to be voted, in favor of the Merger.

#### Opinion of TFC s Financial Advisor(page [ ])

In connection with the Merger, the TFC board of directors received an oral and a written opinion, dated September 9, 2013, from TFC s financial advisor, Keefe, Bruyette & Woods, a Stifel Company (KBW), to the effect that, as of the date of the opinion and based on and subject to the various considerations described in the opinion, the Merger Consideration described in the Merger Agreement was fair, from a financial point of view, to the holders of TFC common stock. The full text of KBW s written opinion, which sets forth, among other things, the assumptions made, procedures followed, matters considered, and limitations on the review undertaken by KBW in rendering its opinion, is attached to this document as <u>Annex B</u>. We encourage you to read the entire opinion carefully. The opinion of KBW is directed to the TFC board of directors and does not constitute a recommendation to any TFC shareholder as to how to vote at the TFC special meeting or any other matter relating to the proposed Merger.

Reasons for the Merger (page [ ])

The TFC board of directors determined that the Merger Agreement and the Merger Consideration were in the best interests of TFC and its shareholders and recommends that TFC shareholders vote in favor of the approval of the Merger Agreement and the transactions contemplated by the Merger Agreement.

In its deliberations and in making its determination, the TFC board of directors considered many factors including, but not limited to, the following:

• the business, earnings, operations, financial condition, management, prospects, capital levels, and asset quality of both Old National and TFC;

• the increased regulatory burdens on financial institutions, the effects of the expected continued operation of Tower Bank & Trust Company under applicable regulatory restrictions and the uncertainties in the regulatory climate going forward;

- Old National s access to capital and managerial resources relative to that of TFC;
- the board s desire to provide TFC shareholders with the prospects for greater future appreciation on their investments in TFC common stock than the amount the board of directors believes TFC could achieve independently;
- the financial and other terms and conditions of the Merger Agreement, including the fact that the Merger Consideration (assuming no adjustments) represents a premium of approximately 180% to TFC s tangible book value as of the date of the Merger Agreement; and

• the financial analyses prepared by KBW, TFC s financial advisor, and the opinion dated as of September 9, 2013, delivered to the TFC board by KBW, to the effect that the Merger Consideration described in the Merger Agreement is fair, from a financial point of view, to TFC s

shareholders.

• Old National s community banking orientation and its perceived compatibility with TFC.

Old National s board of directors concluded that the Merger Agreement is in the best interests of Old National and its shareholders. In deciding to approve the Merger Agreement, Old National s board of directors considered a number of factors, including, but not limited to, the following:

• TFC s community banking orientation and its perceived compatibility with Old National and its subsidiaries;

• a review of the demographic, economic, and financial characteristics of the markets in which TFC operates, including existing and potential competition and the history of the market areas with respect to financial institutions;

• management s review of regulatory restrictions affecting TFC and Tower Bank & Trust Company and management s assessment of the conditions giving rise to such restrictions; and

• management s review of the business, operations, earnings, and financial condition, including capital levels and asset quality, of TFC and Tower Bank & Trust Company.

Regulatory Approvals (page [ ])

Under the terms of the Merger Agreement, the Merger cannot be completed until Old National receives necessary regulatory approvals, which include the approval of the Office of the Comptroller of the Currency and the Board of Governors of the Federal Reserve System (the Federal Reserve Board ). Old National has filed applications with each

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regulatory authority to obtain the approvals. Old National cannot be certain when such approvals will be obtained or if they will be obtained.

New Old National Shares Will be Eligible for Trading (page [ ])

The shares of Old National common stock to be issued in the Merger will be eligible for trading on the NASDAQ Global Market.

Conditions to the Merger (page [ ])

The obligation of Old National and TFC to consummate the Merger is subject to the satisfaction or waiver, on or before the completion of the Merger, of a number of conditions, including:

approval of the Merger Agreement at the special meeting by a majority of the issued and outstanding shares of TFC common stock;

• approval of the transaction by the appropriate regulatory authorities;

• the representations and warranties made by the parties in the Merger Agreement must be true and correct in all material respects as of the effective date of the Merger or as otherwise required in the Merger Agreement unless the inaccuracies do not or will not result in a Material Adverse Effect (as defined below in The Merger Agreement Conditions to the Merger );

• the covenants made by the parties must have been fulfilled or complied with in all material respects from the date of the Merger Agreement through and as of the effective time of the Merger;

the parties must have received the respective closing deliveries of the other parties to the Merger Agreement;

• the Registration Statement on Form S-4, of which this proxy statement/prospectus is a part, relating to the Old National shares to be issued pursuant to the Merger Agreement, must have become effective under the Securities Act, and no stop order suspending the effectiveness of the Registration Statement shall have been issued or threatened by the Securities and Exchange Commission;

• Old National and TFC must have received an opinion from Krieg DeVault LLP, counsel to Old National, dated as of the effective date, to the effect that the Merger constitutes a tax-free reorganization for purposes of Section 368 and related sections of the Internal Revenue Code, as amended;

• Old National must have received a letter of tax advice, in a form satisfactory to Old National, from TFC s independent certified public accounting firm to the effect that any amounts that are paid by TFC or Tower Bank & Trust Company before the effective time of the Merger, or required under TFC s employee benefit plans or the Merger Agreement to be paid at or after the effective time, to persons who are disqualified individuals under Section 280G of the Internal Revenue Code with respect to TFC, Tower Bank & Trust Company or their successors, and that otherwise should be allowable as deductions for federal income tax purposes, should not be disallowed as deductions for such purposes by reason of Section 280G of the Code;

• the shares of Old National common stock to be issued in the Merger shall have been approved for listing on the NASDAQ Global Market;

- there shall be no legal proceedings initiated or threatened seeking to prevent completion of the Merger; and
- TFC shall not have delinquent loans (computed in accordance with the Merger Agreement) in excess of \$24 million;
- TFC s consolidated shareholders equity (computed in accordance with the Merger Agreement) shall not be less than \$57,117,844.

We cannot be certain when, or if, the conditions to the Merger will be satisfied or waived, or that the Merger will be completed.

Termination (page [ ])

Old National or TFC may mutually agree at any time to terminate the Merger Agreement without completing the Merger, even if the TFC shareholders have approved it. Also, either party may decide, without the consent of the other party, to terminate the Merger Agreement under specified circumstances, including if the Merger is not consummated by June 30, 2014, if the required regulatory approvals are not received or if the TFC shareholders do not approve the Merger Agreement at the TFC special meeting. In addition, either party may terminate the Merger Agreement if there is a breach of the agreement by the other party that would cause the failure of conditions to the terminating party s obligation to close, unless the breach is capable of being cured and is cured within thirty (30) days of notice of the breach. TFC also has the right to terminate the Merger Agreement if it receives a proposal which its board of directors determines is superior to the Merger with Old National.

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Further, Old National has the right to terminate the Merger Agreement if the TFC board fails to publicly reaffirm its recommendation of the Merger Agreement, the Merger or the other transactions contemplated in the Merger Agreement within five business days of a written request by Old National to provide such reaffirmation.

Additionally, TFC has the right to terminate the Merger Agreement if Old National s average common stock closing price during the ten trading days preceding the date on which all regulatory approvals approving the Merger are received is below \$10.85 per share, and the decrease in stock price is more than 20% greater than the decrease in the NASDAQ Bank Index during the same time period; provided, however, that Old National will have the right to prevent TFC s termination by agreeing to increase the Exchange Ratio pursuant to a formula set forth in the Merger Agreement.

Termination Fee (page [ ])

TFC is required to pay Old National a \$4,500,000 termination fee in the following circumstances:

• if Old National terminates the Merger Agreement because the TFC board of directors fails to include its recommendation to approve the Merger in the proxy statement/prospectus delivered to shareholders, or makes an adverse recommendation as to the Merger, or approves or publicly recommends another acquisition proposal to the TFC shareholders, or TFC enters into or publicly announces its intent to enter into a written agreement in connection with another acquisition proposal;

• if the TFC Board fails to publicly reaffirm its recommendation of the Merger Agreement, the Merger or the other transactions contemplated in the Merger Agreement within five business days of a written request by Old National to provide such reaffirmation;

• if either party terminates the Merger Agreement because the TFC shareholders fail to approve the Merger Agreement or if Old National terminates the Merger Agreement because a quorum could not be convened at TFC s shareholder meeting called to approve the Merger, and, within the twelve months following the termination, TFC or any of its subsidiaries enters into another acquisition agreement or consummates another acquisition, provided, however, that in such case TFC shall only be liable to pay Old National the amount of the termination fee less the amount of any previously paid Old National expenses; or

• if either party terminates the Merger Agreement because the Merger is not consummated by June 30, 2014 and either prior to the date of termination an acquisition proposal was made for TFC or within the next twelve months TFC or any of its subsidiaries enters into another acquisition agreement or consummates another acquisition.

In the event that the Merger Agreement is terminated by either party as a result of the failure of TFC s shareholders to approve the Merger Agreement and the Merger by the requisite vote or by Old National if a quorum could not be convened at the meeting of shareholders of TFC or at a reconvened meeting held at any time prior to or on June 30, 2014, then TFC shall promptly (but in any event within two business days) remit payment to Old National following receipt of an invoice therefor all of Old National s actual and reasonably documented out of pocket fees and expenses (including reasonable legal fees and expenses) actually incurred by Old National and its affiliates on or prior to the termination of the Merger Agreement in connection with the transactions contemplated by the Merger Agreement as directed by Old National in writing.

You should be aware that some of TFC s directors and executive officers may have interests in the Merger that are different from, or in addition to, their interests as shareholders. TFC s board of directors was aware of these interests and took them into account in approving the Merger Agreement. For example, Old National will assume all obligations under the Employment Agreements, Change in Control Agreements and Retention Agreements for certain employees of TFC and Tower Bank & Trust Company. Further, certain executive officers will receive retention bonuses upon reaching certain milestones.

Additionally, Old National is obligated under the Merger Agreement to provide continuing indemnification to the officers and directors of TFC and Tower Bank & Trust Company for a period of six years following the Merger and to provide such directors and officers with directors and officers liability insurance for a period of one year.

#### Accounting Treatment of the Merger (page [ ])

The Merger will be accounted for as a purchase transaction in accordance with United States generally accepted accounting principles.

Rights of Shareholders After the Merger (page [ ])

When the Merger is completed, TFC shareholders, whose rights are governed by TFC s articles of incorporation and by-laws, will become Old National shareholders, and their rights then will be governed by Old National s articles of

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incorporation and by-laws. Both Old National and TFC are organized under Indiana law. To review the differences in the rights of shareholders under each company s governing documents, see Comparison of the Rights of Shareholders .

#### Tax Consequences of the Merger (page [ ])

Old National and TFC expect the Merger to qualify as a reorganization for U.S. federal income tax purposes. If the Merger qualifies as a reorganization, then, in general, for U.S. federal income tax purposes:

• TFC shareholders will recognize gain (but not loss) in an amount equal to the lesser of (A) the amount of cash received in the Merger, and (B) the excess, if any, of (1) the sum of the amount of cash and the fair market value of the Old National common stock received in the Merger over (2) the TFC shareholder s aggregate tax basis in its TFC common stock surrendered in exchange for Old National common stock; and

• a TFC shareholder will recognize gain or loss, if any, on any fractional shares of Old National common stock for which cash is received equal to the difference between the amount of cash received and the TFC shareholder s allocable tax basis in the fractional shares.

To review the tax consequences of the Merger to TFC shareholders in greater detail, please see the section Material Federal Income Tax Consequences beginning on page [].

#### **Comparative Per Share Data**

The following table shows information about our book value per share, cash dividends per share, and diluted earnings (loss) per share, and similar information as if the Merger had occurred on the date indicated, all of which is referred to as pro forma information. In presenting the comparative pro forma information for certain time periods, we assumed that we had been merged throughout those periods and made certain other assumptions.

The information listed as Pro Forma Equivalent TFC Share was obtained by multiplying the Pro Forma Combined amounts by a fixed Exchange Ratio of 1.20. We present this information to reflect the fact that TFC shareholders will receive shares of Old National common stock for each share of TFC common stock exchanged in the Merger. We also anticipate that the combined company will derive financial benefits from the Merger that include reduced operating expenses and the opportunity to earn more revenue. The pro forma information, while helpful in illustrating the financial characteristics of the merged company under one set of assumptions, does not reflect these benefits and, accordingly, does not attempt to predict or suggest future results. Further, the pro forma information below includes one-time expenses related to the Merger. The pro forma information also does not necessarily reflect what the historical results of the combined company would have been had our companies been combined during these periods.

		TFC Historical		Pro Forma Combined		Pro Forma Equivalent TFC Share
\$ 11.51	\$	13.27	\$	11.65	\$	13.98
\$ 11.81	\$	13.46	\$	11.81	\$	14.17
\$ 0.30	\$	0.47	\$	0.30	\$	0.36
\$ 0.36	\$	0.61	\$	0.36	\$	0.43
\$ 0.75	\$	1.21	\$	0.75	\$	0.90
\$ 0.95	\$	1.18	\$	0.88	\$	1.06
\$ \$ \$ \$ \$	National Historical   \$ 11.51   \$ 11.81   \$ 0.30   \$ 0.36   \$ 0.75	National Historical   \$ 11.51 \$   \$ 11.81 \$   \$ 0.30 \$   \$ 0.306 \$   \$ 0.36 \$	National Historical TFC Historical   \$ 11.51 \$ 13.27   \$ 11.81 \$ 13.46   \$ 0.30 \$ 0.47   \$ 0.36 \$ 0.61   \$ 0.75 \$ 1.21	National Historical TFC Historical   \$ 11.51 \$ 13.27 \$ \$ 11.81   \$ 13.46 \$   \$ 0.30 \$ 0.47 \$ \$ 0.36   \$ 0.37 \$ 1.21	National Historical TFC Historical Pro Forma Combined   \$ 11.51 \$ 13.27 \$ 11.65   \$ 11.81 \$ 13.46 \$ 11.81   \$ 0.30 \$ 0.47 \$ 0.30   \$ 0.36 \$ 0.61 \$ 0.30   \$ 0.75 \$ 1.21 \$ 0.75	National Historical TFC Historical Pro Forma Combined   \$ 11.51 \$ 13.27 \$ 11.65 \$   \$ 11.81 \$ 13.46 \$ 11.81 \$   \$ 0.30 \$ 0.47 \$ 0.30 \$   \$ 0.30 \$ 0.47 \$ 0.30 \$   \$ 0.30 \$ 0.61 \$ 0.36 \$   \$ 0.75 \$ 1.21 \$ 0.75 \$

#### Market Prices and Share Information

The following table presents quotation information for Old National common stock on the NASDAQ Global Market and TFC common stock on the NASDAQ Global Market on September 6, 2013, and November 29, 2013. September 6, 2013, was the last business day prior to the announcement of the signing of the Md align="left" valign="bottom" width="71%" style="border-bottom: #ccffcc;">

Cash flows from financing activities:

Payment of long-term debt

\$	
	-
\$	(4,102
) Collection of advance receivable	
	-
	1,464
Proceeds from exercise of stock warrants	,
	672
	072
	-
Proceeds from sale of stock, net of issuance costs	
	12,593
	10,270
Net cash provided by financing activities	
\$	12.245
	13,265
\$	7,632

Net increase in cash and cash equivalents

	691
	2,918
Cash and cash equivalents at beginning of period	
	3,827
	3,646
Cash and cash equivalents at end of period	
\$	4,518
\$	( 5 ( )
Supplemental disclosures of non-cash investing and financing cash flow information:	6,564
Issuance of common stock for accounts payable and accrued expenses	
\$	
	209
\$	229
Issuance of common stock for debt conversion and debt payments	
\$	024
¢	834
\$	-
Issuance of common stock for patents and royalty interest	
\$	770
\$	
	-
Unrealized gains on investments	
\$	79
\$	222
Supplemental disclosure of cash flow information:	332
Cash paid during the year for interest	
\$	
÷	145

\$

See accompanying notes to consolidated financial statements.

## HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## NOTE 1: BASIS OF PRESENTATION

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has three domestic subsidiaries BioPro Corp., BioAegean Corp. and Core Biotech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., established in Belgium in 1998, has limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

In the opinion of management, all adjustments necessary for a fair presenta-tion of such consolidated financial statements have been included. Such adjust-ments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission (SEC), and do not contain certain information which will be included in our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2006, as filed with the SEC on March 19, 2007.

## NOTE 2: NET LOSS PER SHARE

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, which amounted to 26,693,497 and 17,456,937 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2006 and 2007, respectively, since their effect is antidilutive.

## NOTE 3: EQUITY BASED COMPENSATION

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. The fair values of the options granted, were estimated based on the following weighted average assumptions:

Nine Months Ended September 30,				
	2006		2007	
	4.3% - 4.97%		4.0 - 4.90%	
	-		-	
	2.5-5 yrs		5 yrs	
	72.06%-79.3%		71.64 - 77.57%	
\$	2,197,000	\$	2,238,000	
	Г \$	2006 4.3% - 4.97% 2.5-5 yrs 72.06%-79.3%	2006 4.3% - 4.97% 2.5-5 yrs 72.06%-79.3%	

Stock option activity during the nine months ended September 30, 2007, is as follows:

Stock option activity for employees:

			Weighted Average	
		Weighted	Remaining	
	Number	Average	Contractual	Aggregate
	of	Exercise	Term	Intrinsic
	Options	Price	(Years)	Value
Outstanding December 31,				
2006	2,001,969 \$	2.51	8.01	
Options granted	2,504,120	2.84	9.98	
Options forfeited	(411)	-	-	
Outstanding September 30,				
2007	4,505,678	2.69	8.88	-
Exercisable September 30,				
2007	4,376,692	2.71	6.36	-

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 was \$1,803,000.

Unvested stock option activity for employees:

		Average		
		Weighted	Remaining	
	Number	Average	Contractual	Aggregate
	of	Exercise	Term	Intrinsic
	Options	Price	(Years)	Value
Outstanding December 31,				
2006	113,986	\$ 2.26	9.05	
Options granted	15,000	1.78	10.00	
Options forfeited	-	-	-	-
Outstanding September 30,				
2007	128,986	\$ 2.20	8.94	-

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31,	r			
2006	1,326,732	\$ 2.63	8.18	
Options granted	583,750	\$ 2.02	10.00	
Options forfeited	-	-	-	
Outstanding September 30, 2007	1,910,482	\$ 2.44	8.56	-

Exercisable September 30,				
2007	1,873,382	\$ 2.46	8.66	-

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 was \$413,000.

			Weighted	
			Average	
		Weighted	Remaining	
	Number	Average	Contractual	Aggregate
	of	Exercise	Term	Intrinsic
	Options	Price	(Years)	Value
Outstanding December 31,				
2006	37,100	\$ 2.28	9.81	
Options granted	-	-	-	
Options forfeited	-	-	-	-
Outstanding September 30,				
2007	37,100	\$ 2.28	9.31	-

Unvested stock option activity for non-employees during the year:

The impact on the Company's results of operations of recording equity based compensation for the nine months ended September 30, 2007 was to increase general and administrative expenses by approximately \$2,262,000 and reduce earnings per share by \$0.03 per basic and diluted share.

As of September 30, 2007, there was \$80,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan. Shares issued upon the exercising of stock options are to be issued from previously authorized shares within the Company's Equity Incentive Plan.

#### **Note 4: SHORT TERM INVESTMENTS**

Securities classified as available for sale consisted of:

September 30, 2007									
		Unrealized							
Name of Security		Cost		Market Value		Gain	Maturity Date		
FHLMC	\$	1,051,000	\$	1,093,000	\$	42,000	November, 2007		
FHLMC		960,000		998,000		38,000	October, 2007		
FNMA		800,000		828,000		28,000	December, 2007		
FNMA		3,000,000		3,110,000		110,000	November, 2007		
FHLMC		3,099,000		3,209,000		110,000	December, 2007		
HSBC Finance		1,004,000		1,030,000		26,000	December, 2007		
General Electric		98,000		1,022,000		24,000	December, 2007		
	\$	10,912,000	\$	11,290,000	\$	378,000			
10									

				Unrealized	Maturity
Name of security	Cost	Ν	larket Value	Gain (Loss)	Date
AIG Discount Commercial	\$ 972,000	\$	983,000	\$ 11,000	April, 2007
Natexis Banques Popolare	969,000		979,000	10,000	May, 2007
American General Finance	965,000		974,000	9,000	June, 2007
Daimler Chrysler	965,000		974,000	9,000	June, 2007
LaSalle Bank	965,000		974,000	9,000	June, 2007
General Electric	1,240,000		1,242,000	2,000	July, 2007
HSBC Finance	1,000,000		1,000,000	-	August, 2007
American General Finance	976,000		987,000	11,000	September, 2007
General Electric	965,000		974,000	9,000	September, 2007
General Electric	1,202,000		1,200,000	(2,000)	September, 2007
FHLMC	960,000		960,000	-	October, 2007
FHLMC	1,051,000		1,051,000	-	November, 2007
FNMA	3,000,000		2,991,000	(9,000)	November, 2007
FHLMC	3,099,000		3,086,000	(13,000)	December, 2007
	\$ 18,329,000	\$	18,375,000	\$ 46,000	

#### December 31, 2006

No investment securities were pledged to secure public funds at September 30, 2007 and December 31, 2006, respectively.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at September 30, 2007 and December 31, 2006.

	September 30, 2007							
			-					
		Less Than 12	Months	Lon	iger	Total		
Name of	Number of		Unrealize	ed	Unrealized		Unrealized	
Security	Securities	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss	
FHLMC	1	\$1,093,000	\$ -	\$ -	\$ -	\$1,093,000	\$ -	
FHLMC	1	998,000	-	-	-	998,000	-	
FNMA	1	828,000	-	-	-	828,000	-	
FNMA	1	3,110,000	-	-	-	3,110,000	-	
FHLMC	1	3,209,000	-	-	-	3,209,000	-	
HSBC Finance	1	1,030,000	-	-	-	1,030,000	-	
General Electric	1	1,022,000	-	-	-	1,022,000	-	
Total Temporary Impairment	-	-	-	-	-	-	-	
Securities	7 5	\$ 11,290,000	\$ -	\$ -	\$ - \$	11,290,000	\$ -	
11								

Name of	Number of		Unrealized	Fair	Unrealized		Unrealized
Security	Securities	Fair Value	Loss	Value	Loss	Fair Value	Loss
AIG Discount Commercial	1 \$	983,000	\$ -	\$ -	\$-	\$ 983,000	\$ -
Natexis Banques Popolare	1	979,000	-	-	-	979,000	-
American General Finance	1	974,000	-	-	-	974,000	-
Daimler Chrysler	1	974,000	-	-	-	974,000	-
LaSalle Bank	1	974,000	-	-	-	974,000	-
General Electric	1	1,242,000	-	-	-	1,242,000	-
HSBC Finance	1	1,000,000	-	-	-	1,000,000	-
American General Finance	1	987,000	-	-	-	987,000	-
General Electric	1	974,000	-	-	-	974,000	-
General Electric	1	1,200,000	(2,000)	-	-	1,200,000	(2,000)
FHLMC	1	960,000	-	-	-	960,000	-
FHLMC	1	1,051,000	-	-	-	1,051,000	-
FNMA	1	2,991,000	(9,000)	-	-	2,991,000	(9,000)
FHLMC	1	3,086,000	(13,000)	-	-	3,086,000	(13,000)
Total Temporary Impairment							
Securities	14 \$	18,375,000	\$ (24,000)	\$ -	\$ -	\$ 18,375,000	\$ (24,000)

December 31, 2006 Less than 12 months 12 months or longer

Total

In management's opinion, the unrealized losses reflect changes in interest rates subsequent to the acquisition of specific securities. The Company has the ability to hold these securities until maturity or market price recovery. Management believes that the unrealized losses represent temporary impairment of the securities.

#### Comprehensive Income

The Company reports comprehensive income, which includes net loss, as well as certain other items, which result in a charge to equity during the period.

	Three months ended September 30 (in thousands)				Nine months ended September 30 (in thousands)		
		2006		2007	2006		2007
Unrealized gains (losses) during the							
period	\$	136	\$	180 \$	300	\$	671
Realized loss (gains) during the period		(191)		(118)	(105)		(339)
Other comprehensive income(loss)	\$	(55)	\$	62 \$	195	\$	332

There are no income tax effects allocated to comprehensive income as the Company has no tax liabilities due to net operating losses.

#### **Note 5: DEBENTURE FINANCING**

Long term debt consists of the following:

	Decemb	December 31, 2006		er 30, 2007
October 2003	\$	2,071	\$	-
January 2004		1,031		-
July 2004		1,000		-
Total		4,102		-
Less Discounts		(231)		-
Total		3,871		-
Less current portion		3,871		-
<b>.</b>				
Long term debt	\$	-	\$	-

In June 2007, the Company retired all remaining debt related to its convertible debentures issued in October 2003, January 2004 and July 2004. Of the outstanding debt of approximately \$4,102,000, only \$2,638,000 was required to be paid in new funds to retire the debentures, with the balance being covered by the Company's advance receivable held as collateral by one of the debenture holders.

#### **October 2003 Debentures**

The discount on the October 2003 Debentures was fully amortized; therefore, the Company did not record any financing costs for the three and nine months ended September 30, 2006 and 2007, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the October 2003 Debentures was approximately \$37,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$108,000 and \$72,000, respectively.

#### **January 2004 Debentures**

The discount on the January 2004 Debentures was fully amortized; therefore, the Company did not record financing costs for the three months ended September 30, 2006 and 2007, respectively. Financing costs for the nine months ended September 30, 2006 and 2007, was approximately \$49,000 and \$0, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the January 2004 Debentures was approximately \$7,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, with regard to the January 2004 Debentures was approximately \$7,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$59,000 and \$9,000, respectively.

#### July 2004 Debentures

The Company recorded financing costs for the three months ended September 30, 2006 and 2007, with regard to the July 2004 Debentures of \$116,000 and \$0 respectively. For the nine months ended September 30, 2007, the Company recorded financing costs of \$369,000 and \$231,000, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the July 2004 Debentures was approximately \$16,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, with regard to the July 2004 Debentures was approximately \$16,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$87,000 and \$35,000, respectively.

#### **NOTE 6: EQUITY FINANCING**

For the nine months ended September 30, 2007, Fusion Capital has purchased from the Company 5,750,530 shares for aggregate gross proceeds of approximately \$10,270,000 pursuant to the April 2006 common stock purchase agreement between the Company and Fusion Capital.

#### NOTE 7: ASSET HELD FOR SALE

Asset held for sale consists of equipment purchases related to the purified water system that was to be installed at the Company's manufacturing facility in New Brunswick, NJ. The Company reevaluated its manufacturing needs and determined the installation of a purified water system would not be cost effective; therefore, the Company plans to sell this equipment and reclassified this as an asset held for sale. In addition, the Company recorded an impairment charge of \$68,000 to bring the carrying value of the asset to its net realizable value of \$610,000 as of September 30, 2007 as per SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets".

#### NOTE 8: RECENT ACCOUNTING PRONOUNCEMENTS

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") effective January 1, 2007. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". The cumulative effect of applying the provisions of this interpretation are required to be reported separately as an adjustment to the opening balance of retained earnings in the year of adoption. The adoption of this standard did not have an impact on the financial condition or the results of our operations.

On February 15, 2007, the FASB issued FASB Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115. This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. This option is available to all entities, including not-for-profit organizations. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The FASB's stated objective in issuing this standard is as follows: "to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions".

The fair value option established by Statement 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. A not-for-profit organization will report unrealized gains and losses in its statement of activities or similar statement. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments.

Statement 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The impact of this statement has not been determined.

#### NOTE 9: SUBSEQUENT EVENT

On October 10, 2007, we filed a New Drug Application with the FDA for using Ampligen® to treat Chronic Fatigue Syndrome.

#### ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### Special Note Regarding Forward-Looking Statements

Certain statements in this document constitute "forwarding-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact, included in this report regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including but not limited to, the risk factors discussed below, which may cause the actual results, performance or achievements of Hemispherx and its subsidiaries to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this report. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

#### **Overview**

#### <u>General</u>

We are a biopharmaceutical company engaged in the clinical development, manufacture and marketing of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based acute and chronic disorders. We were founded in the early 1970s, as a contract researcher for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of acute and chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey. Our flagship products include Ampligen® and Alferon N Injection®.

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and clinical testing for treatment/prevention of avian and seasonal influenza. We have completed Phase III clinical trials using Ampligen® to treat ME/CFS patients. On October 10, 2007, we filed a New Drug Application with the FDA for using Ampligen to treat CFS.

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection® is also in clinical development for treating West Nile Virus ("WNV").

#### **New Accounting Pronouncements**

We adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") effective January 1, 2007. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". The cumulative effect of applying the provisions of this interpretation are required to be reported separately as an adjustment to the opening balance of retained earnings in the year of adoption. The adoption of this standard did not have an impact on our financial condition or the results of our operations.

On February 15, 2007, the FASB issued FASB Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115. This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. This option is available to all entities, including not-for-profit organizations. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The FASB's stated objective in issuing this standard is as follows: "to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions".

The fair value option established by Statement 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. A not-for-profit organization will report unrealized gains and losses in its statement of activities or similar statement. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments.

Statement 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The impact of this statement has not been determined.

#### **Disclosure About Off-Balance Sheet Arrangements**

None.

#### **Critical Accounting Policies**

There have been no material changes in our critical accounting policies and estimates from those disclosed in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2006.

#### **RESULTS OF OPERATIONS**

#### Three months ended September 30, 2006 versus three months ended September 30, 2007

#### <u>Net loss</u>

Our net loss of approximately \$5,718,000 for the three months ended September 30, 2007 was \$1,911,000 higher when compared to the same period in 2006. This increase in loss was primarily due to the combination of:

- 1) Higher General & Administrative expenses of \$2,232,000 principally related to an increase in non-cash equity based compensation;
- 2) Higher Research and Development costs of approximately \$228,000 due to the use of outside consultants related to the filing of our NDA for Ampligen®;
- 3) An increase of \$346,000 in other income due to a reversal of accrued liquidated damages in 2006 with respect to our debentures as a result of our failure to timely file our 2005 Annual Report on Form 10-K. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007; and
- 4)Lower interest expense and financing costs of \$295,000 relating to the amortization of debt discounts on our convertible debentures.

Net loss per share was \$0.08 for the current period versus \$0.06 for the same period in 2006.

#### **Revenues**

Revenues for the three months ended September 30, 2007 were \$285,000 as compared to revenues of \$232,000 for the same period in 2006. Ampligen® sold under the cost recovery clinical program was down \$9,000 or 21% and Alferon N Injection<sup>®</sup> sales increased \$62,000 or 33% as compared to the prior period. Ampligen® sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen® and 2) collection of clinical data relating to the patients' treatment and results. We altered our marketing strategy for Alferon N Injection<sup>®</sup> by relaunching the product via a collaborative marketing initiative between Hemispherx and a national Specialty Pharmacy network encompassing specialty pharmacists, pharmacies and targeted physician specialists. This effort was intended to focus our efforts in the most appropriate and productive market segment for the product. This initiative has had a positive impact on Alferon® revenues in the current quarter.

#### Production costs/cost of goods sold

Production/cost of goods sold decreased approximately \$92,000 or 30% for the three months ended September 30, 2007 compared to the same period in 2006. This decrease was primarily due to: 1) lower production costs of approximately \$40,000 relating to excess production capacity during the prior period as more effort was directed toward Ampligen® research and development and 2) a decrease in costs of goods sold of approximately \$51,000. Cost of goods sold for the three months ended September 30, 2006 and 2007 were \$161,000 and \$121,000, respectively. The primary reason for this decrease in cost of goods sold with a corresponding increase in sales can be attributed to a price increase per vial of Alferon N Injection® coupled with a decrease in the number of vials sold during the current period.

#### **Research and Development costs**

Overall research and development costs for the three months ended September 30, 2007 were \$2,740,000 as compared to \$2,512,000 for the same period a year ago representing an increase of \$228,000 or 9%. This increase was primarily due to higher outside consulting fees related to the preparation and filing of our NDA for Ampligen®.

Our research and development costs include the direct cost associated with our effort to develop our experimental compound, Ampligen®, as a therapy in treating acute and chronic diseases. In addition to the costs related to the collection and processing of clinical data, our current expenditures include the costs of establishing our in-house polymer production facility and costs related to preparation and completion of our NDA for the use of Ampligen® in treating CFS.

On October 10, 2007, we filed our NDA with the Food and Drug Administration for using Ampligen® in the treatment of CFS. This filing covers some 1,200 enrolled subjects and approximately 90,000 doses of Ampligen®. There is currently no approved treatment for CFS, which affects over one million people in the United States according to the Centers for Disease Control and Prevention ("CDC"). CFS is a debilitating disease with symptoms consisting of extreme fatigue, short term memory impairment, tender lymph nodes, muscle and joint pain and unrefreshed sleep. Symptom severity varies between patients. According to the CDC, there are no specific diagnostic tests available. Over its developmental history Ampligen® has received various designations including Orphan Drug Product Designation and Emergency (compassionate) Cost Recovery Sales Authorization from the FDA. Pursuant to the mutual recognition procedure we plan to proceed with filing New Drug Applications in the European Union.

We are actively engaged in broad-based experimental studies assessing the efficacy of our products, Ampligen®, Alferon N Injection® and Alferon® LDO against influenza viruses as an adjuvant and/or single agent antiviral with the Defence R&D Canada, the National Institute of Infectious Disease in Tokyo and various research affiliates of the National Institutes of Health in the United States. Articles have recently appeared in the peer-reviewed medical and scientific literature.

In September 2007, Japan's National Institute of Infectious Disease ("JNIID") initiated research on the co-administration of JNIID's HIV-1 vaccine with our experimental TLR3 agonist a substance that binds to a specific receptor and triggers a host defense response in the cell) and immune enhancer, Ampligen®. This research is the result of earlier research suggesting a potential role for Ampligen® in boosting responses to certain vaccines designed to combat avian influenza (Bird Flu) as well as seasonal influenza viruses. The objective of this research is to determine if Ampligen® can overcome the historical problem which has handicapped AIDS vaccine development, namely marginal immune response which undermines the potential of long-lasting protection. Ampligen® will be combined with HIV recombinant protein and administered via an intranasal route.

In October 2007, JNIID published, in two peer reviewed journals, the results of their studies to evaluate the ability of current seasonal influenza vaccine to confer cross-protection against highly pathogenic H5N1 influenza (Bird Flu) virus in mice. These studies indicate that, as a vaccine enhancer co-administered with their seasonal trivalent influenza vaccine, Ampligen® helps induce a protective effect against H5N1 influenza viruses. As such, Ampligen® as a toll-like receptor 3 agonist may aid in overcoming the problems protecting against mutated strains of the H5N1 virus and of limited supplies of H5N1 virus vaccines. Additional studies to support this conclusion are planned.

In April 2007, Japan's Ministry of Health, Labor and Welfare (MHLW) issued authorization to its National Institute of Infectious Diseases (NIID) approving their budget to advance studies indicating that an H5N1 influenza vaccine co-administered intranasally with Hemispherx's experimental therapeutic, Ampligen® protected against mutated strains of the virus and, further that, the seasonal trivalent influenza vaccine co-administered intranasally with Ampligen® maintained efficacy even when challenged with the H5N1 influenza virus.

In June 2007, we initiated a clinical trial in Australia using Ampligen® in combination with seasonal flu vaccine. This trial, expected to continue for several months, is being conducted in Australia's winter season and focuses on populations at risk for virulent cases of influenza, especially those over the age of 60 years who historically may have weakened immune systems. The Australian clinical trial was prompted by the results from the pre-clinical work conducted by the JNIID (see above). Thirty patients are anticipated to be enrolled in this study, which will utilize a two dose Ampligen® regimen of 2 mg per dose. This study is being monitored by Clinical Network Services Pty. Ltd. located in Brisbane, Australia. The clinical trials center of St. Vincent's Hospital based in DarlingHurst, Australia is conducting the trial. Prospective patients are being screened to be included in the clinical trial.

The Center for Disease Control and Prevention reports that the number of mosquito-borne West Nile Virus ("WNV") infections in the United States is "up sharply" over the same period in 2006. This increased infection rate has accelerated the enrollment of patients in our Phase IIb clinical trial using Alferon N<sup>TM</sup> to treat WNV patients. In lab studies, Alferon N<sup>TM</sup>, a natural cocktail of eight alpha-interferons, shows synergistic effects (up to 100 fold over recombinant interferons) against pathogens such as WNV. The Phase IIb clinical trial is a double-blinded, randomized, multi-center program under the direction of Cornell University and Weill Cornell Medical College/New York Hospital.

#### **General and Administrative Expenses**

General and Administrative ("G&A") expenses for the three months ended September 30, 2006 and 2007 were approximately \$1,276,000 and \$3,508,000, respectively, reflecting an increase of \$2,232,000 or 175%. This rise related primarily to an increase in non-cash equity based compensation of \$2,074,000 compared to the same period in 2006 as stock options were granted to officers and directors in the current period which replaced options that had previously expired.

#### **Reversal of Previously Accrued Interest Expense**

Reversal of previously accrued interest expense was \$346,000 for the three months ended September 30, 2007. This item, classified as other income, resulted from the reversal of accrued liquidated damages in 2006 related to a certain covenant in our debenture agreements. These charges were incurred as a result of our failure to timely file our 2005 Annual Report on Form 10-K and our report on Form 10-Q for the quarterly period ended March 31, 2006 with the Securities and Exchange Commission ("SEC") pursuant to the Securities Exchange Act of 1934 (the "1934 Act"). These liquidated damages were not included as part of the maturation and pay down of the debenture holder's outstanding loan balances.

#### **Interest and Other Income and Expense**

Interest and other income and expense for the three months ended September 30, 2006 and 2007 decreased approximately \$237,000 as compared to the same period a year earlier. The decrease in interest and other income during the current period can primarily be attributed to higher interest realized on the maturity of our marketable securities in the prior period. All funds in excess of our immediate need are invested in short-term securities. In addition, we recorded an impairment charge of \$68,000 on an asset that was reclassified as an asset held for sale during the current period. The asset related to equipment purchases for the installation of a purified water system at our manufacturing facility. We re-evaluated our manufacturing needs and determined this installation would not be cost effective; therefore, we classified this equipment as an asset held for sale and adjusted the carrying value of this asset to its net realizable value.

#### **Interest Expense and Financing Costs**

Interest expense and non-cash financing costs were approximately \$4,000 for the three months ended September 30, 2007 versus \$299,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of \$295,000 can be attributed to the incurring of liquidated damages in 2006 payable to our debenture holders resulting from our failure to timely file our 2005 Annual Report on Form 10-K.

Nine months ended September 30, 2006 versus nine months ended September 30, 2007

#### <u>Net loss</u>

Our net loss of approximately \$14,743,000 for the nine months ended September 30, 2007 was slightly lower when compared to the same period in 2006. This \$64,000 reduction in loss was primarily due to the combination of:

1) Higher Research and Development costs of \$920,000 primarily due to an increase in the use of outside consultants related to the preparation and completion of our NDA for the use of Ampligen® in treating CFS;

- 2)Lower interest expense and financing costs of \$653,000 relating to the amortization of debt discounts on our convertible debentures and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from us failing to timely file our 2005 Annual Report on Form 10-K; and
- 3) An increase of \$346,000 in other income due to a reversal of accrued liquidated damages in 2006 with respect to our debentures holders as a result of our failure to timely file our 2005 Annual Report on Form 10-K. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007.

Net loss per share was \$0.21 for the current period versus \$0.24 for the same period in 2006.

#### **Revenues**

Revenues for the nine months ended September 30, 2007 were \$774,000 as compared to revenues of \$715,000 for the same period in 2006. Ampligen® sold under the cost recovery clinical program was down \$39,000 or 27% while Alferon N Injection® sales were up \$98,000 or 17% to \$667,000 during the current period. The increase in Alferon N Injection® sales was due to a price increase instituted this year. Correspondingly, we have experienced a decline in the number of vials sold during the current quarter versus the same period a year ago as we continue to evidence increased competition from rival products.

#### Production costs/cost of goods sold

Production/cost of goods sold was approximately \$767,000 during the current period representing a decrease of approximately \$238,000 or 24% as compared to the same period in 2006. This decrease was primarily due to lower production costs of \$117,000 relating to excess production capacity during the prior period as more effort was directed toward Ampligen® research and development and the NDA; and a decrease in costs of goods sold of \$121,000. Costs of goods sold for the nine months ended September 30, 2006 and 2007 was \$394,000 and \$273,000, respectively.

#### **Research and Development costs**

Overall research and development costs for the nine months ended September 30, 2007 were \$8,450,000 as compared to \$7,530,000 for the same period a year ago representing an increase of \$920,000 or 12%. These costs are primarily related to the collection and processing of clinical data, including the costs of establishing our in-house polymer production facility and the costs of preparing and completing our NDA for the use of Ampligen® in treating CFS. The increase can be attributed to an increase in the use of consultants related to the above areas.

#### **General and Administrative Expenses**

General and Administrative ("G&A") expenses for the nine months ended September 30, 2006 and 2007 were approximately \$6,454,000 and \$6,834,000, respectively, reflecting an increase of \$380,000 or 6%. This increase related primarily to an increase in directors' fees, legal expenses and regulatory filing fees as well as increases in salaries and wages mainly resulting from the hire of our chief operating officer during the 4<sup>th</sup> quarter 2006.

#### **Reversal of Previously Accrued Interest Expense**

Reversal of previously accrued interest expense was \$346,000 for the nine months ended September 30, 2007. This item, classified as other income, resulted from the reversal of accrued liquidated damages in 2006 related to a certain covenant in our debenture agreements. These charges were incurred as a result of our failure to timely file our 2005 Annual Report on Form 10-K and our report on Form 10-Q for the quarterly period ended March 31, 2006 with the SEC pursuant to the 1934 Act. These liquidated damages were not included as part of the maturation and pay down of the debenture holder's outstanding loan balances.

#### **Interest and Other Income and Expense**

Interest and other income and expense for the nine months ended September 30, 2006 and 2007 increased approximately \$68,000 as compared to the same period a year earlier. The increase in interest and other income during the current period was mainly due to higher interest earned upon the maturity of our marketable securities as compared the same period a year ago. This was offset by an impairment charge of \$68,000 recorded in the current period upon the reclassification of equipment to an asset held for sale. We wrote down the carrying value of the equipment to our net realizable value as of September 30, 2007.

#### **Interest Expense and Financing Costs**

Interest expense and non-cash financing costs were approximately \$396,000 for the nine months ended September 30, 2007 versus \$1,049,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of \$653,000 or 62% can be attributed to decreased amortization charges on debt discounts and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from our failure to timely file our 2005 Annual Report on Form 10-K as we were in violation of provisions within our debenture agreements.

#### Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2007 was \$12,007,000. Cash provided by investing activities for the nine months ending September 30, 2007, amounted to \$7,293,000, primarily from the maturity and purchase of short-term investments. Cash provided by financing activities for the nine months ended September 30, 2007 amounted to \$7,632,000. This was primarily due to proceeds received from the sale of our common stock of approximately \$10,270,000. This was offset by the net repayment of our outstanding debt of \$2,638,000 in June 2007. As of October 31, 2007, we had approximately \$17,400,000 in cash and cash equivalents and short-term investments, or a decrease of approximately \$4,621,000 from December 31, 2006. We anticipate that these funds should be sufficient to meet our operating cash requirements for the next 14 months.

In June 2007, we retired all remaining debt related to our convertible debentures issued in October 2003, January 2004 and July 2004. Of the outstanding debt of approximately \$4,102,000, only \$2,638,000 was required to be paid in new funds to retire the debentures, with the balance being covered by other cash and securities already held as collateral for the debentures.

#### **Equity Financing**

On April 12, 2006, we entered into a common stock purchase agreement (the "2006 Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50.0 million over a period of approximately 25 months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, we registered 12,386,723 shares issuable to or issued to Fusion Capital under the Purchase Agreement. Through November 1, 2007, we have sold to Fusion Capital an aggregate of 10,539,112 shares under the common stock purchase agreement for aggregate gross proceeds of \$19,529,128 and issued 447,465 Commitment Shares.

Under the rules of the American Stock Exchange, in the event that we elect to sell more than 12,386,723 shares to Fusion Capital, we were required to seek stockholder approval. This approval was obtained on September 20, 2006. We also will be required to file a new registration statement and have

it declared effective by the SEC in the event we elect to sell to Fusion Capital more than the 12,386,723 shares previously registered.

We are using the proceeds from this financing for general corporate purposes.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen® products.

There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

#### ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately \$17,854,000 in cash and cash equivalents and short-term investments at September 30, 2007. To the extent that our cash and cash equivalents and short term investments exceed our near term funding needs, we generally invest the excess cash in three to twelve month interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. We place our cash and cash equivalents with what management believes to be high credit quality institutions. At times such investments may be in excess of the FDIC insurance limit.

We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

#### **Item 4: Controls and Procedures**

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of September 30, 2007 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the quarter ended September 30, 2007, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

#### Part II – OTHER INFORMATION

#### **Item 1. Legal Proceedings**

In October 2007, in order to protect our minority shareholder position in Ribotech (Pty) Ltd., we filed an Application in the High Court of South Africa naming as respondents Ribotech (Pty) Ltd, Bioclones (Pty) Ltd, the Trustees of the Biopad Trust and the Directors of Ribotech (Pty) Ltd. The Application asks the court to declare that certain minority shareholder protection provisions bound and still bind Ribotech (Pty) Ltd, that the appointment of certain Directors of Ribotech (Pty) Ltd is and was invalid, and that the allotment of certain shares of stock of Ribotech (Pty) Ltd is and was invalid. This Application is currently pending.

See our Form 10-Q for the period ending June 30, 2007 for previously reported legal proceedings.

#### **ITEM 1A. Risk Factors.**

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this Form 10-Q. Among the key factors that have a direct bearing on our results of operations are:

#### **Risks Associated With Our Business**

#### No assurance of successful product development

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

On October 10, 2007 we filed an NDA with the FDA for approval to use Ampligen® in the treatment of Chronic Fatigue Syndrome. We can provide no guidance as to the tentative date at which the filing of the NDA will be accepted or, if accepted, when or if the NDA will be approved. The timing of the FDA review process of the NDA is subject to the control of the FDA and could result in one of the following events; 1) approval to market Ampligen® for use in treating ME/CFS patients 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our NDA application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

Alferon N Injection<sup>®</sup>. Although Alferon N Injection<sup>®</sup> is approved for marketing in the United States for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older; to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments.

### Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly affected.

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval.

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the Evaluation of Medicinal Products ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen® is authorized for use in clinical trials including a cost recovery program in the United States and Europe, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen® or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

# Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.

Ampligen® is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen® in the treatment of avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen® is being tested on two strains of avian influenza virus. There are a number of strains and strains mutate. No assurance can be given that Ampligen® will be effective on any strains that might infect humans.

#### We may continue to incur substantial losses and our future profitability is uncertain.

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of September 30, 2007, our accumulated deficit was approximately \$181,794,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

#### We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of September 30, 2007, we had approximately \$17,850,000 in cash and cash equivalents and short-term investments. We anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 14 months.

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50,000,000 over a 25 month period (see Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources").

We only have the right to receive up to \$100,000 per trading day under the agreement with Fusion Capital unless our stock price exceeds \$1.90 by at least \$0.10, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. We have registered an aggregate of 13,201,840 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares) and, through November 1, 2007, we have sold to Fusion Capital an aggregate of 10,539,112 shares under the common stock purchase agreement for aggregate gross proceeds of approximately \$19,529,128. Assuming a purchase price of \$1.59 per share (the closing sale price of the common stock on November 1, 2007) and the purchase by Fusion Capital of the remaining 1,204,109 shares (after issuing the remaining 196,037 Commitment Shares), total gross proceeds to us from the remaining shares would only be \$1,914,533 (\$21,443,661 in the aggregate under the common stock purchase agreement).

In the event we elect to issue additional shares to Fusion Capital, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In addition, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of Commitment Shares under the common stock purchase agreement.

Accordingly, depending upon the future market price of our common stock, even if we register the balance of the shares issuable to Fusion Capital under the Purchase Agreement, we most likely will realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell Ampligen® and/or increase sales of Alferon N Injection® or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$50,000,000 under the common stock purchase agreement with Fusion Capital, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

#### We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection<sup>®</sup>, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen®, which is carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen® and Ampligen® in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen® in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of AmpligenÒ as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection®, we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon® LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

### The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

# There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

### If our distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our prod-ucts in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in Canada, Spain and Portugal.

We cannot assure that our U.S. or foreign marketing partners will be able to successfully distribute our products, or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues-. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us.

# There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing Alferon N Injection® and/or Ampligen®.

A number of essential materials are used in the production of Alferon N Injection®, including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain polymers on a more consistent manufacturing basis.

If we are unable to obtain or manufacture the required polymers, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen® and the commercial production of Alferon N Injection® and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

### There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

#### We have limited manufacturing experience and capacity.

Ampligen® has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

### We may not be profitable unless we can produce Ampligen® or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facili-ties. If we cannot manufacture commercial quantities of Ampligen® or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

#### Rapid technological change may render our products obsolete or non-competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

#### Our products may be subject to substantial competition.

Ampligen®. Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smith Kline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection<sup>®</sup>. Many competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection® currently competes with Schering's injectable recombinant alpha interferon product (INTRON® A) for the treatment of genital warts. 3M Pharmaceuticals also offer competition from its immune-response modifier, Aldara®, a self-administered topical cream, for the treatment of external genital and perianal warts. In addition, Medigene recently received FDA approval for a self-administered ointment, VeregenTM, which is indicated for the topical treatment of external genital and perianal warts. Alferon N Injection® also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

### Possible side effects from the use of Ampligen® or Alferon N Injection® could adversely affect potential revenues and physician/patient acceptability of our product.

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection<sup>®</sup>. At present, Alferon N Injection<sup>®</sup> is only approved for the intra-lesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection<sup>®</sup>, patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection<sup>®</sup> which could threaten or limit such product's usefulness.

### We may be subject to product liability claims from the use of Ampligen<sup>®</sup>, Alferon N Injection<sup>®</sup>, or other of our products which could negatively affect our future operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appro-priate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen® and/or Alferon N Injection® product liability claims. A successful product liability claim against us in excess of Ampligen®'s \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection®'s \$5,000,000 in aggregate; or for which coverage is not provided could have a negative effect on our business and financial condition.

#### The loss of services of key personnel including Dr. William A. Carter could hurt our chances for success.

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2,000,000 on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

#### Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

#### There are risks of liabilities associated with handling and disposing of hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

#### **Risks Associated With an Investment in Our Common Stock**

#### The market price of our stock may be adversely affected by market volatility.

The market price of our common stock has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

announcements of the results of clinical trials by us or our competitors;

adverse reactions to products;

· governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;

changes in U.S. or foreign regulatory policy during the period of product development: ·developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;

announcements of technological innovations by us or our competitors;

announcements of new products or new contracts by us or our competitors;

• actual or anticipated variations in our operating results due to the level of development expenses and other factors;

· changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

conditions and trends in the pharmaceutical and other industries;

new accounting standards; and .

the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended October 31, 2007, the price of our common stock has ranged from \$1.06 to \$2.49 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

#### Our stock price may be adversely affected if a significant amount of shares are sold in the public market.

We have registered 13,201,840 for sale by Fusion Capital and 143,658 shares by others, and may, in the future, register an additional 15,000,000 shares for sale by Fusion Capital under the common stock purchase agreement. As of November 1, 2007, approximately 208,855 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act. Also, we have registered 6,571,072 shares issuable upon exercise of 135% of certain Warrants and upon exercise of certain other warrants. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

# The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital and other shares registered for selling stockholders could cause the price of our common stock to decline.

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of sales by Fusion Capital and other selling stockholders could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are to be freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by Fusion Capital will be sold over a period of in excess of two years. Depending upon market liquidity at the time, a sale of shares by Fusion at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock to Fusion Capital pursuant to the purchase agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

### Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 8.9% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen® for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.

#### ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds

During the quarter ended September 30, 2007, we issued an aggregate of 47,350 shares for services performed and an aggregate of 51,976 shares for the payment of interest.

All of the foregoing transactions were conducted pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933.

We did not repurchase any of our securities during the quarter ended September 30, 2007.

#### **ITEM 3: Defaults upon Senior Securities**

None.

#### ITEM 4: Submission of Matters to a Vote of Security Holders

None

**ITEM 5: Other Information** 

None.

#### **ITEM 6: Exhibits**

#### (a) Exhibits

- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

#### 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.

#### HEMISPHERx BIOPHARMA, INC.

/S/ William A. Carter William A. Carter, M.D. Chief Executive Officer & President

/S/ Robert E. Peterson Robert E. Peterson Chief Financial Officer

Date: November 7, 2007