BIODELIVERY SCIENCES INTERNATIONAL INC

Form DEF 14A June 26, 2007 Table of Contents

# **SCHEDULE 14A INFORMATION**

# **Proxy Statement Pursuant to**

Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant x	Filed by a Party other than the Registrant "								
Check the appropriate box:									
" Preliminary Proxy Statement									
Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))									
x Definitive Proxy Statement									
" Definitive Additional Materials									
Soliciting Material Pursuant to §240.14a-12									
	BioDelivery Sciences International, Inc.								
(Name of Registrant as Specified In Its Charter)									
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No:	fee required.
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1)	Title of each class of securities to which transaction applies:
2)	Aggregate number of securities to which transaction applies:
3)	Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
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1)	Amount Previously Paid:
2)	Form, Schedule or Registration Statement No.:
3)	Filing Party:
4)	Date Filed:

June 26, 2007

To the Stockholders of BioDelivery Sciences International, Inc.:

BioDelivery Sciences International, Inc. (the **Company**) is pleased to send you the enclosed notice of the 2007 Annual Meeting of Stockholders of the Company (the **Meeting**) to be held at 11 a.m. on Thursday, July 26, 2007 at the Marriott Courtyard Raleigh-Durham Airport, 2001 Hospitality Court, Morrisville, NC 27560.

The items of business for the Meeting are listed in the following Notice of Annual Meeting and are more fully addressed in the attached Proxy Statement. The Proxy Statement is first being mailed to stockholders of the Company on or about June 29, 2007.

Your vote is important please date, sign and return your proxy card in the enclosed envelope as soon as possible to ensure that your shares will be represented and voted at the Meeting even if you cannot attend. If you attend the Meeting, you may vote your shares in person even though you have previously signed and returned your proxy.

If you have any questions regarding this material, please do not hesitate to call me at (919) 653-5160.

Sincerely yours,

Francis E. O Donnell, Jr.

Chairman of the Board of Directors

BioDelivery Sciences International, Inc.

WHETHER OR NOT YOU EXPECT TO ATTEND THE MEETING, PLEASE COMPLETE THE ENCLOSED PROXY CARD AND PROMPTLY MAIL IT IN THE ENCLOSED ENVELOPE IN ORDER TO ASSURE REPRESENTATION OF YOUR SHARES AT THE MEETING.

#### BIODELIVERY SCIENCES INTERNATIONAL, INC.

2501 Aerial Center Parkway, Suite 205

Morrisville, NC 27560

#### NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

To be held on Thursday, July 26, 2007

The 2007 Annual Meeting of Stockholders (the **Meeting**) of BioDelivery Sciences International, Inc. (the **Company**) will be held at 11 a.m. on Thursday, July 26, 2007, at the Marriott Courtyard Raleigh-Durham Airport, 2001 Hospitality Court, Morrisville, NC 27560, for the following purposes:

- 1. To elect all seven (7) members of the Company s Board of Directors to serve until the 2008 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
- 2. To ratify the appointment by the Audit Committee of the Company s Board of Directors of Aidman Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2007; and
- 3. To transact such other business as may properly come before the meeting or any adjournment thereof. Stockholders are cordially invited to attend the Meeting in person. However, to assure your representation at the Meeting, please complete and sign the enclosed proxy card and return it promptly. Even if you have previously submitted a proxy card you may choose to vote in person at the Meeting. Whether or not you expect to attend the Meeting, please read the attached proxy statement and then promptly complete, date, sign and return the enclosed proxy card in order to ensure your representation at the Meeting.

The Board of Directors unanimously recommends a vote for the approval of each of the proposals to be submitted at the meeting.

BY ORDER OF THE BOARD OF DIRECTORS

James A. McNulty, CPA

Secretary, Treasurer and Chief Financial Officer

Morrisville, North Carolina

June 26, 2007

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#### BIODELIVERY SCIENCES INTERNATIONAL, INC.

2501 Aerial Center Parkway, Suite 205

Morrisville, NC 27560

(919) 653-5160

PROXY STATEMENT

ANNUAL MEETING OF STOCKHOLDERS

to be held on Thursday, July 26, 2007, 11 a.m.

**Marriott Courtyard Raleigh-Durham Airport** 

2001 Hospitality Court

Morrisville, NC 27560

# QUESTIONS AND ANSWERS ABOUT THESE PROXY MATERIALS

## Why am I receiving this proxy statement?

This proxy statement describes the proposals on which our Board of Directors would like you, as a stockholder, to vote at our annual meeting of the stockholders, which will take place on Thursday, July 26, 2007 at 11 a.m. local time at Marriott Courtyard Raleigh-Durham Airport, 2001 Hospitality Court, Morrisville, NC 27560.

This proxy statement also gives you information on these proposals so that you can make an informed decision. We intend to mail this proxy statement and accompanying proxy card on or about June , 2007 to all stockholders of record entitled to vote at the annual meeting.

In this proxy statement, we refer to BioDelivery Sciences International, Inc. as the Company, we, us or our.

## Who can vote at the annual meeting of stockholders?

Stockholders who owned shares of our common stock, par value \$.001 per share ( **Common Stock** ), on June 26, 2007 (the **Record Date** ) may attend and vote at the annual meeting. Each share is entitled to one vote. There were 18,925,426 shares of Common Stock outstanding on the Record Date. All shares of Common Stock shall vote together as a single class. Information about the stockholdings of our directors and executive officers is contained in the section of this proxy statement entitled Beneficial Ownership of Principal Stockholders, Officers, and Directors on page of this proxy statement.

## What is the proxy card?

The proxy card enables you to appoint Mark A. Sirgo, our President and Chief Executive Officer, and/or James A. McNulty, our Secretary, Treasurer and Chief Financial Officer, as your representative at the annual meeting. By completing and returning the proxy card, you are authorizing these persons to vote your shares at the annual meeting in accordance with your instructions on the proxy card. This way, your shares will be voted whether or not you attend the annual meeting. Even if you plan to attend the annual meeting, we think that it is a good idea to complete and return your proxy card before the annual meeting date just in case your plans change. If a proposal comes up for vote at the annual meeting that is not on the proxy card, the proxies will vote your shares, under your proxy, according to their best judgment.

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## What am I voting on?

You are being asked to vote on the election of the members of our Board of Directors and the ratification of our independent registered public accounting firm for the fiscal year ending December 31, 2007. We will also transact any other business that properly comes before the annual meeting.

#### How does the Board of Directors recommend that I vote?

Our Board of Directors unanimously recommends that the stockholders vote for the nominees for director and for the ratification of our independent registered public accounting firm for the fiscal year ending December 31, 2007.

#### What is the difference between holding shares as a stockholder of record and as a beneficial owner?

Most of our stockholders hold their shares in an account at a brokerage firm, bank or other nominee holder, rather than holding share certificates in their own name. As summarized below, there are some distinctions between shares held of record and those owned beneficially.

#### Stockholder of Record

If, on the Record Date, your shares were registered directly in your name with our transfer agent, American Stock Transfer & Trust Company, you are a stockholder of record who may vote at the annual meeting, and we are sending these proxy materials directly to you. As the stockholder of record, you have the right to direct the voting of your shares by returning the enclosed proxy card to us or to vote in person at the annual meeting. Whether or not you plan to attend the annual meeting, please complete, date and sign the enclosed proxy card to ensure that your vote is counted.

#### Beneficial Owner

If, on the Record Date, your shares were held in an account at a brokerage firm or at a bank or other nominee holder, you are considered the beneficial owner of shares held in street name, and these proxy materials are being forwarded to you by your broker or nominee who is considered the stockholder of record for purposes of voting at the annual meeting. As the beneficial owner, you have the right to direct your broker on how to vote your shares and to attend the annual meeting. However, since you are not the stockholder of record, you may not vote these shares in person at the annual meeting unless you receive a valid proxy from your brokerage firm, bank or other nominee holder. To obtain a valid proxy, you must make a special request of your brokerage firm, bank or other nominee holder. If you do not make this request, you can still vote by using the voting instruction card enclosed with this proxy statement; however, you will not be able to vote in person at the annual meeting.

#### How do I Vote?

#### (1) You may vote by mail.

You may vote by mail by completing, signing and dating your proxy card and returning it in the enclosed, postage-paid and addressed envelope. If we receive your proxy card prior to the annual meeting and if you mark your voting instructions on the proxy card, your shares will be voted:

as you instruct, and

according to the best judgment of the proxies if a proposal comes up for a vote at the annual meeting that is not on the proxy card.

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If you return a signed card, but do not provide voting instructions, your shares will be voted:

for the seven (7) nominees to our Board of Directors, all of whom are presently serving on the board;

to ratify the appointment of our independent registered public accounting for the fiscal year ending December 31, 2007; and

according to the best judgment of either Dr. Sirgo or Mr. McNulty, if a proposal comes up for a vote at the annual meeting that is not on the proxy card.

### (2) You may vote in person at the annual meeting.

We will pass out written ballots to anyone who wants to vote at the annual meeting. However, if you hold your shares in street name, you must bring to the annual meeting a valid proxy from the broker, bank or other nominee holding your shares that confirms your beneficial ownership of the shares and gives you the right to vote your shares. Holding shares in street name means you hold them through a brokerage firm, bank or other nominee, and therefore the shares are not held in your individual name. We encourage you to examine your proxy card closely to make sure you are voting all of your shares in the Company.

## What does it mean if I receive more than one proxy card?

You may have multiple accounts at the transfer agent and/or with brokerage firms. Please sign and return all proxy cards to ensure that all of your shares are voted.

### What if I change my mind after I return my proxy?

You may revoke your proxy and change your vote at any time before the polls close at the annual meeting. You may do this by:

sending a written notice to the Secretary of the Company stating that you would like to revoke your proxy of a particular date;

signing another proxy card with a later date and returning it before the polls close at the annual meeting; or

attending the annual meeting and voting in person.

Please note, however, that if your shares are held of record by a brokerage firm, bank or other nominee, you must instruct your broker, bank or other nominee that you wish to change your vote by following the procedures on the voting form provided to you by the broker, bank or other nominee. If your shares are held in street name, and you wish to attend the annual meeting and vote at the annual meeting, you must bring to the annual meeting a legal proxy from the broker, bank or other nominee holding your shares, confirming your beneficial ownership of the shares and giving you the right to vote your shares.

## Will my shares be voted if I do not sign and return my proxy card?

If your shares are held in street name or in your name and you do not sign and return your proxy card, your shares will not be voted unless you vote in person at the annual meeting.

## How are votes counted?

You may vote for, against, or abstain on each of the election of directors and the ratification of our independent registered public accounting firm.

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## How many votes are required to elect the nominated persons to the Board of Directors?

The affirmative vote of a plurality of the votes cast at the meeting of the stockholders by the holders of shares of common stock entitled to vote in the election are required to elect each director.

#### How many votes are required to ratify the Company s independent public accountants?

The affirmative vote of a majority of the votes cast at the meeting of the stockholders by the holders of shares of common stock entitled to vote are required to ratify Aidman Piser & Company, P.A., as our independent registered public accounting firm for the year ending December 31, 2007.

#### How many votes are required to approve other matters that may come before the stockholders at the annual meeting?

An affirmative vote of a majority of the votes cast at the annual meeting is required for approval of all other items being submitted to the stockholders for their consideration.

## What happens if I don t indicate how to vote my proxy?

If you just sign your proxy card without providing further instructions, your shares will be counted as a for vote for the nominees on the proxy card and as a for vote for the ratification of our independent registered public accounting firm for the fiscal year ending December 31, 2007.

#### Is my vote kept confidential?

Proxies, ballots and voting tabulations identifying stockholders are kept confidential and will not be disclosed except as may be necessary to meet legal requirements.

#### Where do I find the voting results of the annual meeting?

We will announce voting results at the annual meeting.

## Who can help answer my questions?

You can contact our Secretary and Chief Financial Officer, Mr. James A. McNulty, at (813) 864-2562 or by sending a letter to Mr. McNulty at offices of the Company at 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606 with any questions about proposals described in this proxy statement or how to execute your vote.

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#### BIODELIVERY SCIENCES INTERNATIONAL, INC.

2501 Aerial Center Parkway, Suite 205

Morrisville, NC 27560

(919) 653-5160

#### PROXY STATEMENT

#### INTRODUCTION

2007 Annual Meeting of Stockholders

This Proxy Statement is being furnished to holders of shares of common stock, \$.001 par value (the **Common Stock**) of BioDelivery Sciences International, Inc., a Delaware corporation (the **Company**), in connection with the solicitation of proxies by the Board of Directors of the Company (the **Board of Directors**) for use at the 2007 Annual Meeting of Stockholders of the Company (the **Meeting**). The Meeting is to be held at 11 a.m. on Thursday, July 26, 2007 at the Marriott Courtyard Raleigh-Durham Airport, 2001 Hospitality Court, Morrisville, NC 27560, and at any adjournment or adjournments thereof.

Record Date; Mailing Date

The Board of Directors has fixed the close of business on June 26, 2007 (the **Record Date**) as the record date for the determination of stockholders entitled to notice of, and to vote and act at, the Meeting. Only stockholders of record at the close of business on that date are entitled to notice of, and to vote and act at, the Meeting. The Proxy Statement is first being mailed to stockholders of the Company on or about June 29, 2007.

Proposals to be Submitted at the Meeting

At the Meeting, Stockholders will be acting upon the following proposals:

- 1. To elect all seven (7) members of the Company s Board of Directors to serve until the 2008 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
- 2. To ratify the appointment by the Audit Committee of the Board of Directors of Aidman Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2007; and
- 3. To transact such other business as may properly come before the meeting or any adjournment thereof. *Principal Offices*

The principal executive offices of the Company are located at 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560. The telephone number is (919) 653-5160.

Information Concerning Solicitation and Voting

As of the Record Date, there were 18,925,426 outstanding shares of Common Stock, each share entitled to one vote on each matter to be voted on at the Annual Meeting. Only holders of shares of Common Stock on the Record Date will be entitled to vote at the Annual Meeting. The holders of Common Stock are entitled to one vote on all matters presented at the meeting for each share held of record. The presence in person or by proxy of holders of record of a majority of the shares outstanding and entitled to vote as of the Record Date shall be required for a quorum to transact business at the Annual Meeting. If a quorum should not be present, the Annual Meeting may be adjourned until a quorum is obtained.

To be elected, each nominee named in Proposal 1 must receive the vote of a plurality of the votes of the shares of Common Stock present in person or represented by proxy at the meeting. For the purposes of election

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of directors, although abstentions will count toward the presence of a quorum, they will not be counted as votes cast and will have no effect on the result of the vote.

Broker non-votes, which occur when brokers are prohibited from exercising discretionary voting authority for beneficial owners who have not provided voting instructions, will not be counted for the purpose of determining the number of shares present in person or by proxy on a voting matter and will have no effect on the outcome of the vote. Brokers who hold shares in street name may vote on behalf of beneficial owners with respect to Proposals 1, 2, & 3.

#### Expenses

The expense of preparing, printing and mailing this Proxy Statement, exhibits and the proxies solicited hereby will be borne by the Company. In addition to the use of the mails, proxies may be solicited by officers and directors and regular employees of the Company, without additional remuneration, by personal interviews, telephone or facsimile transmission. The Company will also request brokerage firms, nominees, custodians and fiduciaries to forward proxy materials to the beneficial owners of shares of Common Stock held of record and will provide reimbursements for the cost of forwarding the material in accordance with customary charges.

## Revocability of proxies

Proxies given by stockholders of record for use at the Annual Meeting may be revoked at any time prior to the exercise of the powers conferred. In addition to revocation in any other manner permitted by law, stockholders of record giving a proxy may revoke the proxy by an instrument in writing, executed by the stockholder or his attorney authorized in writing or, if the stockholder is a corporation, under its corporate seal, by an officer or attorney thereof duly authorized, and deposited either at the corporate headquarters of the Company at any time up to and including the last business day preceding the day of the Annual Meeting, or any adjournments thereof, at which the proxy is to be used, or with the chairman of such Annual Meeting on the day of the Annual Meeting or adjournments thereof, and upon either of such deposits the proxy is revoked.

ALL PROXIES RECEIVED WILL BE VOTED IN ACCORDANCE WITH THE CHOICES SPECIFIED ON SUCH PROXIES. PROXIES WILL BE VOTED IN FAVOR OF A PROPOSAL IF NO CONTRARY SPECIFICATION IS MADE. ALL VALID PROXIES OBTAINED WILL BE VOTED AT THE DISCRETION OF THE PERSONS NAMED IN THE PROXY WITH RESPECT TO ANY OTHER BUSINESS THAT MAY COME BEFORE THE ANNUAL MEETING.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE FOR THE APPROVAL OF EACH OF THE PROPOSALS TO BE SUBMITTED AT THE MEETING.

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#### PROPOSAL 1

#### **ELECTION OF DIRECTORS**

#### Introduction

The Board of Directors currently consists of one class of directors having seven (7) members. The Board of Directors may determine the total number of directors and the number of directors to be elected at any annual meeting or special meeting in lieu thereof. The Board of Directors has fixed at seven (7) the number of directors to be elected at the Meeting. At the Meeting, stockholders will be asked to elect Francis E.

O Donnell, Jr., Mark A. Sirgo, Raphael J. Mannino, William B. Stone, John J. Shea, William S. Poole and Thomas W. D Alonzo, (the **Nominees**) to serve in such capacity until the 2008 Annual Meeting, or until their successors are duly elected and qualified.

It is the intention of the persons named in the enclosed proxy to vote to elect the Nominees, each of whom is an incumbent director, and each of whom has consented to serve if elected. If some unexpected occurrence should make necessary, in the discretion of the Board of Directors, the substitution of some other person for any of the Nominees, it is the intention of the persons named in the proxy to vote for the election of such other persons as may be designated by the Board of Directors.

## Directors and Executive Officers

Listed below are the names of the directors, executive officers and significant employees of the Company, their ages as of June 26, 2007 and positions held:

eld
the Board and Director
hief Executive Officer and Director
ice President, Chief Scientific Officer and Director
ice President of Product Development
cial Officer, Secretary and Treasurer

There are no family relationships between any director, executive officer or significant employee.

None of the Company s directors or executive officers have been involved, in the past five years, in a fashion material to an evaluation of such director s or officer s ability or integrity to serve as a director or executive officer, in any those Certain Legal Proceedings, more fully detailed in Item 401(d) of Regulation S-B, which include but are not limited to, bankruptcies, criminal convictions and an adjudication finding that an individual violated federal or state securities laws.

Francis E. O Donnell, Jr., M.D., age 57, has been of our Chairman of the Board and a Director since March 29, 2002. Dr. O Donnell has previously served as our President and Chief Executive Officer. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. For more than the last six years, Dr. O Donnell has served as managing director of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. He is a co-founder and chairman of RetinaPharma Technologies, Inc. which now includes Tatton Technologies, LLC, and a co-founder of Biotech Specialty Partners, LLC, an alliance of specialty pharmaceutical and biotechnology companies. He serves as Chairman and CEO of Accentia

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Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. Dr. O Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. Dr. O Donnell holds 34 U.S. Patents. Dr. O Donnell is the 2000 Recipient of the Jules Stein Vision Award sponsored by Retinitis Pigmentosa International. He is a trustee of the Health Careers Foundation and of St Louis University.

Mark A. Sirgo, Pharm.D., age 53, was appointed President and Chief Executive Officer in July of 2005. This followed his appointment as President and Chief Operating Officer in January 2005. He joined the company in August 2004 upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer, in the capacity of Senior Vice President of Commercialization and Corporate Development, and, prior to being named our President, was promoted to Executive Vice President, Corporate and Commercial Development and Chief Operating Officer. Dr. Sirgo has more than 20 years of experience in the pharmaceutical industry, including 16 years in clinical drug development; 7 years in marketing, sales, business development and 5 years in executive management. Prior to his involvement with Arius Pharmaceuticals from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc., (NASDAQ:PPDI) a leading contract service provider to the pharmaceutical industry. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Raphael J. Mannino, Ph.D., age 60, has been our Executive Vice President and Chief Scientific Officer since October 2000, and a Director since October 2001. Dr. Mannino has served as President, CEO, Chief Scientific Officer, and a member of the Board of Directors of BioDelivery Sciences, Inc., our predecessor, since its incorporation in 1995. Dr. Mannino s previous experience includes positions as Associate Professor, at the University of Medicine and Dentistry of New Jersey (1990 to present), Assistant, then Associate Professor, Albany Medical College (1980 to 1990), and Instructor then Assistant Professor, Rutgers Medical School (1977 to 1980). His postdoctoral training was from 1973 to 1976 at the Biocenter in Basel, Switzerland. Dr. Mannino received his Ph.D. in Biological Chemistry in 1973 from the Johns Hopkins University, School of Medicine.

Andrew L. Finn, Pharm.D., age 57, has been our Executive Vice President of Product Development since January 2007. He joined the company in August 2004 upon our acquisition of Arius, of which he was a co-founder, in the capacity of Senior Vice President of Product Development and was subsequently promoted to the position of Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has more than 20 years experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at POZEN Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for two migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of U.S. Clinical Research for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

James A. McNulty, age 56, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis (estimated to constitute approximately 50% of his time) since October 2000. Mr. McNulty has, since May

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2000, also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. Mr. McNulty also serves as the Treasurer and Corporate Secretary of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics, and as Chief Financial Officer for Biovest International, a majority-owned subsidiary of Accentia. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida s largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002 he served as CFO/COO of American Prescription Providers, Inc. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, and is a member of the American and Florida Institutes of CPA s.

William B. Stone, age 64, is a member of our Board of Directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. Mr. Stone is a graduate of the University of Missouri-Columbia where he earned BS and MA degrees in accounting, and is a Certified Public Accountant.

John J. Shea, age 80, is a member of our Board of Directors. He is currently the head of his own firm of John J. Shea & Associates and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has been employed at John J. Shea Associates since 1989. Mr. Shea has also served in the capacity of Director of Quality Assurance and was responsible for the implementation of quality assurance procedures in a number of public companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. Mr. Shea earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 60, is a member of our Board of Directors. He has extensive experience in the biopharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. He later served as President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, and also as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building a solid management team and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly oversaw vice presidents in charge of manufacturing, research & development, sales, legal, marketing, finance, regulatory and human resources functions. In recent years, Mr. Poole has acted as a private consultant and, until his appointment to the board, Mr. Poole served as a member of the Commercial Advisory Board of BDSI s subsidiary, Arius Pharmaceuticals.

Thomas W. D. Alonzo, 63, was appointed to our Board of Directors on August 30, 2006. Mr. D. Alonzo s experience in the biopharmaceutical industry spans more than 30 years as a top-level pharmaceutical executive, and includes all major facets of pharmaceutical operations. From 1983 to 1993, Mr. D. Alonzo worked at Glaxo, Inc., the U.S. subsidiary of the former Glaxo Holdings P.L.C., rising to the position of President of Glaxo from 1988 to 1993. At Glaxo, he served on its board of directors and presided over 4,400 employees, including an 1,800 person sales force in a company that generated \$3 billion dollars in annual revenues. From 1993 to 1996, Mr. D. Alonzo served as President and Chief Executive Officer of GenVec, Inc., a gene therapy biotechnology company. During his tenure at GenVec, two INDs were filed, Theragen, a separate gene therapy company, was acquired, and the company raised \$20 million in funding. From 1996 to 1999, Mr. D. Alonzo served as President

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and Chief Operating Officer of Pharmaceutical Product Development, Inc., a multi-national clinical research organization. At PPDI, he oversaw 3,000 employees in a company that generated \$300 million in revenues. In 1999, Mr. D. Alonzo received his Honorary Doctor of Pharmacy from Campbell University, Buies Creek, North Carolina. He received his BS in Business Administration from University of Delaware and his JD from University of Denver. Since 1999, he served as a board member of other pharmaceutical companies, which currently includes, Salix Pharmaceuticals, Ltd., Amarillo Biosciences, Inc., and Dara Biosciences, Inc.

Certain Relationships and Related Transactions

We have several business relationships with Accentia Biopharmaceuticals, Inc. ( Accentia ) and its affiliates. Hopkins Capital Group II, LLC ( HCG ), which is controlled by Dr. Frank O Donnell, our Chairman of the Board and a director and which owns a significant percentage of our common stock as of the date of this proxy statement, is a significant stockholder of Accentia. In addition, Dr. Donnell is also the Chairman and CEO of Accentia. James A. McNulty, our Secretary, Treasurer and part-time CFO, is the Secretary and Treasurer of Accentia. Dr. Raphael J. Mannino, our Executive Vice President and Chief Scientific Officer, is a director of Biovest International, Inc. (OTC BB:BVTI), a subsidiary of Accentia. Mr. McNulty is also the CFO of HCG and Biovest International.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for the treatment of CRS and asthma on a worldwide basis. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

Arius/TEAMM Distribution Agreement. On March 17, 2004, our subsidiary, Arius Pharmaceuticals, granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., with respect to our Emezine® product for the treatment of nausea and vomiting. TEAMM is a specialty pharmaceutical company and wholly owned subsidiary of Accentia. As part of this agreement, TEAMM has agreed to pay for the development costs of Emezine®. We received development cost reimbursements of \$1.0 million in 2004 from Accentia in connection with this agreement and an additional \$300,000 in 2005 upon the acceptance of the Emezine® NDA for filing.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica \$47,800 for these reports, some of which we paid in 2005.

On April 2, 2007, we obtained a \$1.0 million financing from HCG in the form of an unsecured, non-interest bearing note, due June 30, 2007. The proceeds from this loan were used by us to make a required installment payment to QLT USA Inc. ( QLT ) in connection with our August 2006 purchase of the non-U.S. rights to the BEMA<sup>TM</sup> disc drug delivery technology from QLT. In connection with the loan made by HCG, we granted HCG the right, for a period of six months, to enter into a royalty purchase agreement with us. The consideration to be paid by HCG upon exercise of the right, which can be demanded by us or HCG in our respective discretion at any time before September 30, 2007, is \$5.0 million in cash. If the royalty purchase agreement is entered into, the royalty to be paid to HCG shall be based on a low, single digit, tiered percentage of net sales of BEMA<sup>TM</sup> Fentanyl, once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, we would issue a warrant to HCG to purchase 475,000 shares of our common stock at \$5.55 per share (the closing price on April 2, 2007). No assurances can be given the either we or HCG will elect to enter into the royalty purchase agreement.

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During 2001, we entered into agreements with RetinaPharma, Inc. (now called RetinaPharma Technologies, Inc.) and Tatton Technologies, LLC (now a part of RetinaPharma). Both are biotechnology companies which are developing nutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson s disease. To the extent that such drugs utilize Bioral cochleate technology, we will support drug development and will share in ten percent (10%) of all net revenue from such sales of Bioral® encapsulated drugs. HCG, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O Donnell is the managing director of HCG.

We have also entered into an agreement with Biotech Specialty Partners, LLC, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. Biotech Specialty Partners, LLC is in its formative stage and to date has not distributed any pharmaceutical products. Under this agreement, BSP will serve as a nonexclusive distributor of our Bioral® drugs in consideration of a ten (10%) discount to the wholesale price, which our Board of Directors has determined to be commercially reasonable. BSP has waived its rights under this agreement with respect to Arius products. HCG, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, is affiliated as a member of Biotech Specialty Partners, LLC and Dr. O Donnell is a member of the management of Biotech Specialty Partners, LLC.

On July 19, 2002, we issued Ellenoff Grossman & Schole LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at \$7.00 per share. In 2003, we issued Ellenoff Grossman & Schole LLP 19,607 options to purchaser shares of our common stock at \$2.55 per share as compensation for services rendered. In 2004, we issued Ellenoff Grossman & Schole LLP 44,509 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP has acted as counsel to our inactive subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to promoters as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parities. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present Board of Directors includes four independent directors which constitute a majority as required by the rules of the National Association of Securities Dealers ( NASD ). We believe that William B. Stone, John J. Shea, William S. Poole and Thomas D Alonzo qualify as independent directors for Nasdaq Stock Market purposes.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds \$60,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

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### Code of Ethics

On March 24, 2003, the Board of Directors adopted a code of ethics that applies to the Company s principal executive and financial officers. The Company intends to file amendments, changes or waivers to the code of ethics as required by the rules of the Securities and Exchange Commission (the SEC).

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that the Company's directors and executive officers and persons who beneficially own more than 10% of the Common Stock (referred to herein as the reporting persons) file with the SEC various reports as to their ownership of and activities relating to the Common Stock. Such reporting persons are required by the SEC regulations to furnish the Company with copies of all Section 16(a) reports they file. Based solely upon a review of copies of Section 16(a) reports and representations received by the Company from reporting persons, and without conducting any independent investigation, in 2006, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

## Meetings of the Board of Directors

The Board of Directors met in person and telephonically 13 times during 2006 and also acted by unanimous written consent. It is the Company s policy that all directors must attend all meetings, barring extenuating circumstances. All Nominees were present at seventy-five (75%) percent or more of the Board of Directors meetings held during such director s tenure as a member of the Board of Directors.

## Director Independence

We believe that William B. Stone, John J. Shea, William S. Poole and Thomas D. Alonzo qualify as independent directors for Nasdaq Stock Market purposes. This means that our Board of Directors is composed of a majority of independent directors as required by the rules of the NASD.

### Committees of the Board of Directors

Our Board of Directors has established three standing committees Audit, Compensation, and Nominating and Corporate Governance. The Audit and Nominating and Corporate Governance Committees each operate under a charter that has been approved by the board.

As compensation for their duties, directors receive \$1,000 for appearing in person at a Board of Directors meeting. Compensation also includes 20,000 options to purchase common stock for each year served as a director. Additionally, each director is granted 5,000 options to purchase common stock per year for serving on a committee of the Board of Directors and an additional 5,000 options to purchase common stock per year for serving as chairman of a committee of the Board of Directors.

#### Audit Committee

We have a separately designated standing Audit Committee of the board of directors established in accordance with Section 3(a)(58)(A) of the Exchange Act, which committee is governed by a charter. The Audit Committee met five times during 2006. Each member of the Audit Committee was present at all of the Audit Committee meetings held during such director—s tenure as a member of the Audit Committee. The Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the independence and performance of, and assesses the qualifications of, our independent auditors, and engages such independent auditors. The Audit Committee approves the plan and fees for the annual audit, review of quarterly reports, tax and other audit-related services, and approves in advance any non-audit service to be provided by the

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independent auditors. The Audit Committee monitors the rotation of partners of the independent auditors on our engagement team as required by law. The Audit Committee reviews the financial statements to be included in our Annual Report on Form 10-KSB and reviews with management and the independent auditors the results of the annual audit and our quarterly financial statements. In addition, the audit Committee oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the board. The Audit Committee provides oversight assistance in connection with legal and ethical compliance programs established by management and the board, including Sarbanes-Oxley implementation, and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

The Audit Committee is composed of William B. Stone, John J. Shea and Thomas D. Alonzo, all of whom are independent directors as defined in accordance with section 3(a)(58)(A) of the Exchange Act and the rules of NASDAQ. Mr. Stone serves as chairman of the committee. The Board of Directors has determined that Mr. Stone is an audit committee financial expert as defined in Item 407(d)(5)(ii) of Regulation S-B.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee composed of William S. Poole and John J. Shea and Thomas D. Alonzo. Mr. Shea serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the Board of Directors for consideration. The Nominating and Corporate Governance Committee was formed in May of 2004 and did not meet formally in 2006, although members of the committee were involved with interviews of Mr. D. Alonzo prior to his joining the Board of Directors in September 2006. The Nominating and Corporate Governance Committee has a charter. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASD. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o the Company, Attn: James A McNulty. There are no minimum qualifications for consideration for nomination to be a director of the Company. The nominating committee will assess all director nominees using the same criteria. All of the current nominees to serve as directors on our Board of Directors have previously served in such capacity. During 2006, we did not pay any fees to any third parties to assist in the identification of nominees. During 2006, we did not receive any director nominee suggestions from stockholders.

## Compensation and Investment Committees

Our Board of Directors also has a compensation committee, which, either alone or in conjunction with the full board, as the case may be, reviews or recommends compensation policies for our company and compensation arrangements for our management. The members of the compensation committee are William S. Poole, John J. Shea and William B. Stone. William S. Poole acts as chairman of this committee. The compensation committee met one time during 2006.

Our Board of Directors also has an investment committee, which either alone or in conjunction with the full board, as the case may be, reviews and recommends the investment arrangements for our company. The members of the investment committee are Dr. Francis E. O Donnell and William Stone. The investment committee as such did not meet during 2006.

There are no other Board of Directors committees at this time.

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#### **Audit Committee Report\***

The audit committee of the Board of Directors (the **Committee**) is composed of three directors: William B. Stone, Thomas W. D. Alonzo and John J. Shea, each of whom is independent as defined by the rules of the National Association of Securities Dealers. Mr. Stone serves as chairman of the committee. The Board of Directors has adopted a written Audit Committee Charter, which was filed as Appendix A to the Company s 2003 Proxy Statement.

Management is responsible for the Company s financial statements, financial reporting process and systems of internal controls. The Company s independent auditors are responsible for performing an independent audit of the Company s financial statements in accordance with auditing standards generally accepted in the United States and for issuing a report thereon. The Committee s responsibility is to oversee all aspects the financial reporting process on behalf of the Board of Directors. The responsibilities of the Committee also include engaging and evaluating the performance of the accounting firm that serves as the Company s independent auditors.

The Committee discussed with the Company s independent auditors, with and without management present, such auditors judgments as to the quality, not just acceptability, of the Company s accounting principles, along with such additional matters required to be discussed under the Statement on Auditing Standards No. 61, Communication with Audit Committees. The Committee has discussed with the independent auditors the auditors independence from the Company and its management, including the written disclosures and the letter submitted to the Committee by the independent auditors as required by the Independent Standards Board Standard No. 1, Independence Discussions with Audit Committees.

In reliance on such discussions with management and the independent auditors, review of the representations of management and review of the report of the independent auditors to the Committee, the Committee recommended (and the Board of Directors approved) that the Company s audited financial statements be included in the Company s Annual Report on Form 10-KSB for the year ended December 31, 2006. The Committee and the Board of Directors have also, respectively, recommended and approved the selection of the Company s current independent auditors, which approval is subject to ratification by the Company s stockholders.

Audit Committee of the Board of Directors

/s/ WILLIAM B. STONE
/s/ THOMAS W. D ALONZO
/s/ JOHN J. SHEA

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<sup>\*</sup> The information contained in this Audit Committee Report shall not be deemed to be soliciting material or filed or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Securities Exchange Act, except to the extent that the Company specifically requests that the information be treated as soliciting material or specifically incorporates it by reference into a document filed under the Securities Act or the Securities Exchange Act.

# **Executive Compensation**

Summary Compensation Table

The following table sets forth all annualized compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2006, 2005 and 2004. Individuals we refer to as our named executive officers include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded \$100,000 during the fiscal year ended December 31, 2006, as well as our Chairman of the Board of Directors, Francis E. O. Donnell, Jr.

# SUMMARY COMPENSATION TABLE

						Non-	Equity	Nonqualified		
				Stock	Incentive Plan		Deferred			
		Salary <sup>(1)</sup>	Bonus	Awards	Option	Comp	ensation	Compensation	All Other	
Name and principal position	Year	(\$)	(\$)	(\$)	Awards (\$	) (	(\$)	Earnings (\$) Co	ompensation (\$)	Total (\$)
Mark A. Sirgo, Pharm.D.,	2006	\$ 252,617	0	0	\$ 27,831	\$ 2	21,574(2)	0	\$ 12,668(5)	\$ 314,690
	2005	\$ 202,366	0	0	\$ 129,465	5 \$ 3	34,154(2)	0	\$ 8,750	\$ 374,735
President, Chief Executive										
Officer and Director	2004	\$ 62,596	\$ 31,177	0	\$ 11,062	2	0	0	\$ 1,683	