

BIODELIVERY SCIENCES INTERNATIONAL INC

Form DEF 14A

June 30, 2005

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## SCHEDULE 14A INFORMATION

### Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

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))

Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material Pursuant to §240.14a-12

**BioDelivery Sciences International, Inc.**

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(Name of Registrant as Specified In Its Charter)

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(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

No fee required.

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

1) Title of each class of securities to which transaction applies:

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2) Aggregate number of securities to which transaction applies:

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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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4) Proposed maximum aggregate value of transaction:

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5) Total fee paid:

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Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

1) Amount Previously Paid:

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2) Form, Schedule or Registration Statement No.:

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3) Filing Party:

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4) Date Filed:

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June 30, 2005

To the Stockholders of BioDelivery Sciences International, Inc.:

BioDelivery Sciences International, Inc. (the **Company**) is pleased to send you the enclosed notice of the 2005 Annual Meeting of Stockholders of the Company (the **Meeting**) to be held at 11:00 a.m. on Thursday, July 28, 2005 at the Hilton Garden Inn, Raleigh-Durham Airport, 1500 RDU Center Drive, 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 July 1, 2005.

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 (314) 579-9725.

Sincerely yours,

/s/ Francis E. O' Donnell, Jr.  
**Francis E. O' Donnell, Jr.**

**Chairman and Chief Executive Officer**

**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.**

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**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 28, 2005**

The 2005 Annual Meeting of Stockholders (the **Meeting**) of BioDelivery Sciences International, Inc. (the **Company**) will be held at 11:00 a.m. on Thursday, July 28, 2005, at the Hilton Garden Inn, Raleigh-Durham Airport, 1500 RDU Center Drive, 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 2006 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
2. To approve and ratify the conversion terms of the Company's Series A Convertible Preferred Stock in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii);
3. To approve and ratify the conversion terms of a portion of the Company's Series B Convertible Preferred Stock (aggregated with certain other securities as described in the attached Proxy Statement) in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii);
4. To approve and ratify the conversion terms of the Company's February and May 2005 Convertible Notes and Warrants and June 2005 Warrants issued to Laurus Master Fund, Ltd. in accordance with Nasdaq Marketplace Rule 4350(i)(1)(D)(ii);
5. 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, 2005; and
6. 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.

**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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BY ORDER OF THE BOARD OF DIRECTORS

/s/ James A. McNulty, CPA  
**James A. McNulty, CPA**  
**Secretary, Treasurer and Chief Financial Officer**

Morrisville, North Carolina

June 30, 2005

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**BIODELIVERY SCIENCES INTERNATIONAL, INC.**

2501 Aerial Center Parkway, Suite 205

Morrisville, NC 27560

(919) 653-5160

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**PROXY STATEMENT**

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**ANNUAL MEETING OF STOCKHOLDERS**

**to be held on Thursday, July 28, 2005, 11:00 a.m.**

**Hilton Garden Inn, Raleigh-Durham Airport**

**1500 RDU Center Drive**

**Morrisville, NC 27560**

**INTRODUCTION**

*2005 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 ( **BioDelivery** or 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 2005 Annual Meeting of Stockholders of the Company (the **Meeting** ) to be held at 11:00 a.m. on Thursday, July 28, 2005 at the Hilton Garden Inn, Raleigh-Durham Airport, 1500 RDU Center Drive, 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 28, 2005 (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 July 1, 2005.

*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 2006 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
2. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii), the conversion terms of the Company's Series A Non-Voting Convertible Preferred Stock to the extent that the shares of Common Stock issuable upon conversion of such Series A Convertible Preferred Stock could potentially equate to 20% or more of Common Stock outstanding as of August 24, 2004, the date of issuance;

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3. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii), the conversion terms of the Company's Series B Convertible Preferred Stock to the extent that the shares of Common Stock issuable upon conversion of the first \$1.25 million of such Series B Convertible Preferred Stock, when aggregated with the shares of Common Stock underlying all shares of the Company's Series A Non-Voting Convertible Preferred Stock, could potentially equate to 20% or more of Common Stock outstanding as of August 24, 2004, the deemed date of issuance;
4. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(D)(ii), the conversion terms of the Company's February and May 2005 Convertible Notes and Warrants and June 2005 Warrants issued to Laurus Master Fund, Ltd. to the extent that the shares of Common Stock issuable upon conversion of such securities could potentially equate to 20% or more of Common Stock outstanding as of February 22, 2005, the deemed date of issuance;
5. 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, 2005; and
6. 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 7,269,196 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 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, 4 and 5.

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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.

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.**

[remainder of page intentionally left blank]

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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., Raphael J. Mannino, William B. Stone, John J. Shea, L.M. Stephenson, Alan Pearce and William S. Poole (the **Nominees**) to serve in such capacity until the 2006 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 named above, 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 28, 2005 and positions held:

| <u>Name</u>                     | <u>Age</u> | <u>Position</u>   |
|---------------------------------|------------|---|
| Francis E. O'Donnell, Jr., M.D. | 55         | Chief Executive Officer, Chairman of the Board and Director             |
| Mark A. Sirgo, Pharm.D.         | 51         | President and Chief Operating Officer                                   |
| Raphael J. Mannino, Ph.D.       | 58         | Executive Vice President, Chief Scientific Officer and Director         |
| Andrew L. Finn, Pharm.D.        | 55         | Executive Vice President of Clinical Development and Regulatory Affairs |
| James A. McNulty                | 54         | Chief Financial Officer, Secretary and Treasurer                        |
| Donald L. Ferguson              | 57         | Senior Executive Vice President   |
| L.M. Stephenson, Ph.D.          | 61         | Director  |
| William B. Stone                | 62         | Director  |
| John J. Shea                    | 78         | Director  |
| William S. Poole                | 58         | Director  |
| Alan Pearce                     | 55         | Director  |

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

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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.

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*Francis E. O' Donnell, Jr., M.D.*, age 55, has been the Chief Executive Officer, Chairman and a Director of the Company on a full time basis since March 29, 2002 when Dr. O' Donnell executed an employment agreement to become the Company's full-time interim President and Chief Executive Officer. In January 2005, he relinquished the title of President. 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 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 51, has been the President and Chief Operating Officer of the Company since January 2005. He joined the Company in August 2004 upon the acquisition of Arius, of which he was a co-founder, in the capacity of Senior Vice President of Commercialization and Corporate Development, and, prior to being named 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 and 7 years in marketing, sales, and business development. Prior to his involvement with Arius 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 among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc., 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 58, has been Executive Vice President and Chief Scientific Officer of the Company 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 Science, Inc. 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 55, has been Executive Vice President of Clinical Development and Regulatory Affairs of the Company since September 2004. He joined the Company in August 2004 upon the 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 his current position. 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.

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for 2 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 54, has served as Secretary, Treasurer and Chief Financial Officer of the Company on a part time basis (estimated to constitute approximately 50% of his time) since October 2000. Mr. McNulty has, since May 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. 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 principal in Pinnacle Group Holdings, a Tampa real estate development company. 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 CPAs.

*Donald L. Ferguson*, age 57, has been Senior Executive Vice President of the Company on a part time basis since October 2000. Mr. Ferguson has been Chief Executive Officer and principal owner of Land Dynamics, Inc., a developer of real estate projects since its founding in 1979 and currently owns in excess of 20 real estate properties. Mr. Ferguson is an investor in early stage technology and biotechnology companies including Nanovision Technologies, Inc., Star Scientific, Inc., BioKeys Pharmaceuticals, Inc. (now Adventrx) and PhotoVision Pharmaceuticals, Inc. Mr. Ferguson holds an M.B.A. Degree from the University of Kansas and a B.S. Degree in industrial engineering from Oklahoma State University.

*L.M. Stephenson, Ph.D.*, age 61, is a member of the Board of Directors. Dr. Stephenson is currently Vice Provost for Research at Drexel University. He was associated with the University of Medicine and Dentistry of New Jersey from 1995 until 2003, serving as the Vice President for Research with responsibility over developing the research capability, research funding and intellectual property of New Jersey's medical science campuses, including three medical schools, dental, nursing and public health schools and a graduate school of biomedical sciences. He also served as the Acting Associate Dean for Research of the New Jersey Medical School, and served as the Director of Patents and Licensing of the University of Medicine and Dentistry of New Jersey where he was responsible for management of the Intellectual Property Assets, including marketing of patents and establishment of new ventures. His new responsibilities at Drexel are closely similar to UMDNJ. Dr. Stephenson is a graduate of the University of North Carolina where he earned a BS in chemistry and was awarded the Venable Medal for outstanding senior in chemistry. Dr. Stephenson earned his Ph.D. in chemistry from the California Institute of Technology where he earned the Kodak Prize for outstanding chemistry graduate student and was an NSF Predoctoral Fellow. Additionally, Dr. Stephenson was a Research Fellow at Harvard University. Dr. Stephenson also serves on the board of directors of the following institutions: University City Science Center (Non-Profit), and Crescent Genomics.

*William B. Stone*, age 62, is a member of the 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

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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 78, is a member of the 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 58, was appointed to the Board of Directors on April 28, 2005. He was formerly a member of Arius Commercial Advisory Board. Mr. Poole has extensive experience in the bio-pharmaceutical 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. After a brief stint as President of Fisons Pharmaceuticals, which was acquired by Rhone Poulenc-Rorer, Mr. Poole went on to become President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, where he served from 1997 to 2000. From 2001 to 2003, he served 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. Since his departure from Biovail, Mr. Poole has acted as an independent consultant to the pharmaceutical industry. Mr. Poole graduated from Boston University in 1972 with a B.A. Psychology.

*Alan Pearce*, age 55, is a member of the Board of Directors. Since August 2004, he has served as the Chief Financial Officer of Accentia Biopharmaceuticals, Inc. Prior to this, Mr. Pearce served as Senior Vice President, Financial Services for McKesson Corporation, a large publicly traded healthcare company, from April 1999 to March 2004. Mr. Pearce also currently serves on the advisory boards of The Georgia Institute of Technology, or Georgia Tech, the Emory University BioEngineering Foundation, and The Hopkins Capital Group. He also previously served as a director and a member of the finance committee of XL Insurance. Mr. Pearce is a graduate of Georgia Tech, where he earned a B.S. degree in Industrial Management, and the University of Texas, where he earned an MBA degree in finance.

### *Certain Relationships and Related Transactions*

The above-named directors and executive officers have indicated that neither they nor any of their respective affiliates has any relationship with the Company that is required to be disclosed pursuant to Item 404 of Regulation S-B promulgated under the Securities Exchange Act of 1934, as amended, except for the transactions set forth below.

The Company has several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates ( **Accentia** ). Hopkins Capital Group II LLC, which is controlled by Dr. Frank O. Donnell, the Company's Chairman and CEO and which owns a significant percentage of Common Stock as of the Record Date, as well as all of the Company's Series B Convertible Preferred Stock, is a significant stockholder of



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Accentia. In addition, Dr. Donnell is also the Chairman and CEO of Accentia. Also, Alan Pearce, a member of the Company's Board of Directors, is the CFO of Accentia and James A. McNulty, the Company's Secretary, Treasurer and CFO, is the Treasurer and Corporate Secretary of Accentia.

*Amphotericin B License.* On April 12, 2004, the Company licensed a topical formulation of encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research for the treatment of chronic rhinosinusitis ( **CRS** ) and asthma on a worldwide basis. The license agreement was amended effective June 1, 2004, then modified in September 2004 by the Company's 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. The Company retains world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

*Arius/TEAMM Distribution Agreement.* On March 17, 2004, and prior to its acquisition by the Company, the Company's Arius Pharmaceuticals, Inc. ( **Arius** ) subsidiary granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc. ( **TEAMM** ), with respect to Arius licensed 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®. The Company received development cost reimbursements of \$1.0 million in 2004 from Accentia in connection with this agreement.

*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 the Company. The Company paid Analytica \$47,800 for these reports, some of which was paid in 2005.

Mr. James McNulty, the Company's Secretary, Treasurer and part-time Chief Financial Officer, is also the Chief Financial Officer of Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O. Donnell, the Company's Chief Executive Officer and Chairman.

During 2001, the Company entered into agreements with RetinaPharma, Inc. (now call 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 the Company's Bioral® cochleate technology, the Company will support drug development and will share in ten percent (10%) of all net revenue from such sales of Bioral® encapsulated drugs. Hopkins Capital Group II, LLC, one of the Company's significant stockholders, and Dr. Francis E. O. Donnell, Jr., the Company's Chief Executive Officer and Chairman, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O. Donnell is the managing director of Hopkins Capital Group II, LLC.

The Company has also entered into an agreement with Biotech Specialty Partners, LLC ( **BSP** ), an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. BSP 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 the Company's Bioral® drugs in consideration of a ten (10%) discount to

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the wholesale price, which the Board of Directors has determined to be commercially reasonable. BSP has waived its rights under this agreement with respect to Arius products. Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O'Donnell, Jr., the Company's Chairman and CEO, are affiliated as stockholders, and a member of the management, of Biotech Specialty Partners, LLC.

On July 19, 2002, the Company issued Ellenoff Grossman & Schole LLP, its outside legal counsel, 25,000 options to purchase shares of Common Stock at \$7.00 per share. In 2004, the Company issued Ellenoff Grossman & Schole LLP 44,510 shares of Common Stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to the Company's subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares 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, the Company has 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.

The Company believes that the terms of the above transactions with affiliates were as favorable to the Company or affiliates as those generally available from unaffiliated third parties. At the time of certain of the above referenced transactions, the Company did not have sufficient disinterested directors to ratify or approve the transactions; however, the present Board of Directors includes four independent directors. These independent directors are currently William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole.

All future transactions between the Company and its 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 the independent directors who do not have an interest in the transactions and who had access, at the Company's expense, to the Company's legal counsel or independent legal counsel.

To the best of the Company's 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 the Company is or may 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 the Company to own of record or beneficially more than 5% of any class of the Common Stock, or any member of the immediate family of any of the foregoing persons, has an interest.

### *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*

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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 2004, all Forms 3, 4 and 5 were not timely filed with the SEC by such reporting persons. The Company believes there are some delinquent filings in 2005.

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### *Meetings of the Board of Directors*

The Board of Directors met in person and telephonically ten times during 2004 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 75% or more of the Board of Directors meetings held during such director's tenure as a member of the Board of Directors.

### *Director Independence*

The Board of Directors has determined that each of Messrs. Stone, Stephenson, Shea and Poole qualify as an independent director under the current corporate governance rules of the Nasdaq Stock Market.

### *Committees of the Board of Directors*

The 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 of Directors.

### *Audit Committee*

The Board of Directors has an Audit Committee, composed of William B. Stone, L.M. Stephenson and John J. Shea, all of whom are independent directors as defined by the rules of the National Association of Securities Dealers ( **NASD** ). 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 401(e) of Regulation S-B.

The Audit Committee met eight times during 2004. 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 the Company's 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, the Company's 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 independent auditors. The Audit Committee monitors the rotation of partners of the independent auditors on the engagement team as required by law. The Audit Committee reviews the financial statements to be included in the Company's Annual Report on Form 10-KSB and reviews with management and the independent auditors the results of the annual audit and the Company's quarterly financial statements. In addition, the Audit Committee oversees all aspects the Company's 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.

*Nominating and Corporate Governance Committee*

The Board of Directors has a Nominating and Corporate Governance Committee, composed of William B. Stone, L.M. Stephenson and John J. Shea. Mr. Stone serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing the Company's 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

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2004 and did not formally meet during 2004. 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 have previously served in such capacity. During 2004, the Company did not pay any fees to any third parties to assist in the identification of nominees. During 2004, the Company did not receive any director nominee suggestions from stockholders.

*Compensation and Investment Committees*

The Board of Directors also has a compensation committee, which, either alone or in conjunction with the full board, as the case may be, reviews and recommends the compensation arrangements for Company management. The members of the compensation committee are Dr. Francis E. O'Donnell, Jr., L.M. Stephenson and William B. Stone. The compensation committee as such did not meet during 2004.

The 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 the Company. The members of the investment committee are Dr. Francis E. O'Donnell, William Stone, L.M. Stephenson and Alan Pearce. The investment committee as such did not meet during 2004.

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, L.M. Stephenson 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 of 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, 2004. 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/ L. M. STEPHENSON

/s/ JOHN J. SHEA

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\* 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.

**Table of Contents***Compensation of Directors and Executive Officers*

The following table provides certain summary information concerning compensation paid to the named executive officers and directors for the years stated.

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 10,000 options to purchase Common Stock per year for serving as a chairman of a committee of the Board of Directors and 5,000 options to purchase Common Stock per year for serving on a committee of the Board of Directors.

**SUMMARY COMPENSATION TABLE\***

| (a)<br>Name and<br>Principal Position                                      | (b)<br>Year | Long Term Compensation             |              |                        |  |   |                        |                                  |
|--|-------------|------------------------------------|--------------|------------------------|--|---|------------------------|----------------------------------|
|  |             | Annual Compensation <sup>(1)</sup> |              |                        | Awards                                 |   | Payouts                |                                  |
|  |             | (c)<br>Salary                      | (d)<br>Bonus | (e)<br>Other           | (f)<br>Restricted<br>Stock<br>Award(s) | (g)<br>Securities<br>Underlying<br>Options/SARs | (h)<br>LTIP<br>Payouts | (i)<br>All Other<br>Compensation |
|  |             |                                    |              | Annual<br>Compensation |  |   |                        |                                  |
|  |             | (\$)                               | (\$)         | (\$)                   | (\$)                                   | (#)   | (\$)                   | (\$)                             |
| Francis E. O. Donnell, Jr., M.D.   | 2004        | \$ 117,692                         |              |                        |  | 35,000  |                        |                                  |
| Chief Executive Officer and Chairman                                       | 2003        | 145,962                            |              |                        |  | 35,000  |                        |                                  |
|  | 2002        | 112,500                            |              |                        |  | 61,991  |                        |                                  |
| 709 The Hampton Lane<br>Chesterfield, MO 63017                             |             |                                    |              |                        |  |   |                        |                                  |
| Mark A. Sirgo, Pharm. D. <sup>(2)</sup> ,                                  | 2004        | \$ 62,596                          | \$ 31,177.90 |                        |  | 5,147   |                        |                                  |
| President and Chief Operating Officer                                      | 2003        |                                    |              |                        |  |   |                        |                                  |
|  | 2002        |                                    |              |                        |  |   |                        |                                  |
| 3100 Stone Gap Court<br>Raleigh, North Carolina 27612                      |             |                                    |              |                        |  |   |                        |                                  |
| Andrew L. Finn, Pharm. D. <sup>(3)</sup> ,                                 | 2004        | \$ 62,596                          | \$ 28,092.04 |                        |  | 5,147   |                        |                                  |
| Executive Vice President of Clinical<br>Development and Regulatory Affairs | 2003        |                                    |              |                        |  |   |                        |                                  |
|  | 2002        |                                    |              |                        |  |   |                        |                                  |
| 737 West Hargett Street  |             |                                    |              |                        |  |   |                        |                                  |



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Raleigh, NC 27603

|  |      |            |        |  |        |  |
|--|------|------------|--------|--|--------|--|
| James A. McNulty,                                | 2004 | \$ 105,866 | \$     |  | 3,235  |  |
|  | 2003 | 141,769    |        |  | 18,616 |  |
| Chief Financial Officer, Secretary and Treasurer | 2002 | 170,922    | 35,000 |  |        |  |

4419 W. Sevilla Street

Tampa, FL 33629

|   |      |           |        |        |         |          |
|---|------|-----------|--------|--------|---------|----------|
| Raphael J. Mannino, Ph.D. <sup>(4)</sup> ,            | 2004 | \$ 88,788 | \$     | 11,423 | 26,176  | \$ 5,015 |
|   | 2003 | 90,000    | 52,500 |        | 111,449 | 5,015    |
| Executive Vice President and Chief Scientific Officer | 2002 | 91,500    |        |        | 35,423  | 5,015    |

UMDNJ New Jersey Medical School

185 South Orange Avenue, Building 4

Newark, NJ 07103

\* Salary reflects total compensation paid to these executives.

(1) Except as reflected in column (e) with respect to Dr. Mannino, the annual amount of perquisites and other personal benefits, if any, did not exceed the lesser of \$50,000 or 10% of the total annual salary reported for each named executive officer and has therefore been omitted.

(2) Dr. Sirgo joined the Company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of \$175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.

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- (3) Dr. Finn joined the Company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of \$175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.
- (4) Includes: (a) a car allowance of \$6,750 and 401(k) matching of \$4,673 paid in 2004 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). Excludes \$126,286, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2004 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

*Option Grants During Year Ended December 31, 2004*

| (a)<br>Name               | Individual Grants                                       |   | (d)<br>Exercise<br>or<br>Base<br>Price (\$/Sh) | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term |             |             |
|---------------------------|---|---|--|--|-------------|-------------|
|                           | (b)   | (c)   |  | (e)  | (f)         | (g)         |
|                           | Number of Securities Underlying Options/SARs Granted(#) | Percent of Total Options/SARs Granted to Employees in Fiscal Year |  | Expiration Date  | 5%(\$)      | 10%(\$)     |
| Francis E. O Donnell, Jr. | 35,000  | 12.04%  | \$ 2.29  | August 29, 2014  | \$ 4,007.50 | \$ 8,015.00 |
| Mark A. Sirgo             | 5,147   | 1.77%   | \$ 3.40  | October 21, 2014   | \$ 874.99   | \$ 1,749.98 |
| Andrew L. Finn            | 5,147   | 1.77%   | \$ 3.40  | October 21, 2014   | \$ 874.99   | \$ 1,749.98 |
| Raphael J. Mannino        | 6,176   | 2.12%   | \$ 3.40  | October 21, 2014   | \$ 1,049.92 | \$ 2,099.84 |
|                           | 20,000  | 6.887%  | \$ 2.29  | August 29, 2014  | \$ 2,290.00 | \$ 4,580.00 |
| James A. McNulty          | 3,235   | 1.11%   | \$ 3.40  | October 21, 2014   | \$ 549.95   | \$ 1,099.90 |

In July and August 2004, certain of directors exercised an aggregate of 160,000 options to acquire shares of Common Stock. The Company raised \$272,000 from such exercises.

**AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR  
AND FY-END OPTION/SAR VALUES**

| Name and Principal Position     | Shares Acquired On Exercise(#) | Value Realized(\$) | Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) | Value of Unexercised Unexercisable   |
|---------------------------------|--------------------------------|--------------------|--|--|
|                                 |                                |                    | Exercisable<br>Unexercisable   | In-The-Money Options/SARs At Fiscal Year-End(\$)<br>Exercisable<br>Unexercisable |
| (a)                             | (b)                            | (c)                | (d)  | (e)  |
| Francis E. O Donnell, Jr., M.D. | 35,000                         |                    | 105,000/0  | \$ 46,734/0  |

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|                           |                |    |             |
|---------------------------|----------------|----|-------------|
| Mark A. Sirgo, Pharm.D.   | 0/5,147        | \$ | 0/617       |
| Andrew L. Finn, Pharm.D.  | 0/5,147        | \$ | 0/617       |
| Raphael J. Mannino, Ph.D. | 242,016/27,142 | \$ | 197,558/741 |
| James A. McNulty          | 6,206/15,645   | \$ | 0/388       |

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### *Employment Agreements*

Except as set forth below, the Company currently has no written employment agreements with any of its officers, directors or key employees. All directors and officers have executed confidentiality and non-compete agreements with the Company.

The following is a description of the Company's current executive employment agreements:

(a) Dr. Francis E. O'Donnell, Chief Executive Officer and Chairman On March 29, 2002, Dr. O'Donnell executed an employment agreement to be the Company's full-time President and CEO at an annual salary of \$150,000. Dr. O'Donnell's term of employment was to be no longer than three years or until another CEO candidate is appointed. However, in January 2005, the Company entered into an amendment to Dr. O'Donnell's employment agreement pursuant to which: (i) he agreed to serve solely in the position of CEO and Chairman of the Board, (ii) the term of his employment was extended until March 22, 2008 and (iii) his annual salary was, effective February 1, 2005, reduced to \$1.00.

(b) Mark A. Sirgo, Pharm.D., President and Chief Operating Officer On August 24, 2004, Dr. Sirgo executed a three-year employment agreement to be the Company's Senior Vice President of Commercial and Corporate Development and the President of Arius at an annual salary of \$175,000. He was subsequently promoted twice and now holds the position of President and Chief Operating Officer of the Company. Dr. Sirgo also received a signing bonus in the amount of \$31,177.90 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(c) Andrew L. Finn, Pharm.D., Executive Vice President of Clinical Development and Regulatory Affairs On August 24, 2004, Dr. Finn executed a three-year employment agreement to be the Company's Senior Vice President of Product Development and the Senior Vice President and Chief Operating Officer of Arius at an annual salary of \$175,000. He was subsequently promoted and now holds the position of Executive Vice President of Clinical Development and Regulatory Affairs of the Company. Dr. Finn also received a signing bonus in the amount of \$28,092.04 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(d) James A. McNulty, CPA, Chief Financial Officer, Secretary and Treasurer Although he is a part-time CFO, Mr. McNulty has an employment agreement with the Company (which was amended on August 31, 2002 and subsequently in June 2003) for a base salary of \$185,000, reduced to \$110,000 in June 2003, which agreement terminates on June 15, 2006. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(e) Dr. Raphael Mannino, Ph.D., Executive Vice President and Chief Scientific Officer On September 1, 2002, Dr. Mannino executed an employment agreement with the Company at an annual salary of \$210,000. Such agreement terminates on September 1, 2005. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Dr. Mannino had outstanding debt payable to the Company that was incurred with his purchase of stock in the Company's predecessor, BioDelivery Sciences, Inc., in 1999. Simultaneously with the closing of the Company's public offering in June 2002, the Company forgave those notes and provided Dr. Mannino with a total of approximately \$200,000 as compensation for his tax liability.

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Effective April 14, 2005, Dr. Susan Gould-Fogerite, the Company's Vice President and Director of Innovation and Discovery, resigned from the Company. Previously, in November 2004, Dr. Gould-Fogerite accepted a permanent employment position at The University of Medicine and Dentistry of New Jersey.

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Simultaneously with her resignation, the Company agreed with Dr. Gould-Fogerite to terminate her employment agreement, and in connection therewith, the Company entered into a termination agreement and release with her and made a one-time payment to her of \$7,708.68. In addition, the Company entered into a consulting agreement with Dr. Gould-Fogerite pursuant to which, through November 15, 2005, Dr. Gould-Fogerite will continue to consult with the Company on matters relating to the Company's patent estate for up to 8 hours per week at an hourly rate of \$150. Finally, effective April 14, 2005, the Company terminated Dr. Gould-Fogerite's 58,057 of Company incentive stock options and entered into a new option agreement with her pursuant to which the Company granted her 58,057 non-qualified options (at the same exercise prices as her former incentive stock options), which options terminate on November 15, 2007.

*Recommendation of the Board of Directors*

**THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF EACH OF; FRANCIS E. O DONNELL, JR., M.D.; RAPHAEL J. MANNINO, PH.D.; L.M. STEPHENSON, PH.D.; WILLIAM B. STONE; JOHN J. SHEA; WILLIAM S. POOLE AND ALAN PEARCE TO SERVE ON THE COMPANY'S BOARD OF DIRECTORS UNTIL THE 2006 ANNUAL MEETING OR UNTIL THEIR SUCCESSORS ARE DULY ELECTED AND QUALIFIED.**

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**PROPOSAL 2**

**APPROVAL OF CONVERSION TERMS OF THE COMPANY'S**

**SERIES A CONVERTIBLE PREFERRED STOCK IN ACCORDANCE WITH**

**NASDAQ MARKETPLACE RULE 4350(i)(1)(C)(ii)**

*Background*

The purpose of Proposal 2 is to obtain the stockholder approval necessary under applicable Nasdaq Stock Market rules to allow for the full conversion of shares of the Company's Series A Non-Voting Convertible Preferred Stock (the **Series A Preferred**).

*Summary*

As part of the Company's acquisition of Arius Pharmaceuticals, Inc. (**Arius**) in August 2004, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of Series A Preferred, a newly designated, non-voting and non-interest bearing, series of convertible preferred stock. The new Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of Common Stock on a one for one basis at a price equal to \$4.25. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius' first proposed product (ii) 30 days notice to us of a Conversion Event (hereinafter defined) or (iii) five (5) years from the closing date of the acquisition (i.e., August 24, 2009). The term "Conversion Event" is defined in the Certificate of Designation of the Series A Preferred to mean the failure of the Company to provide at least \$3.0 million to Arius as required to: (i) pay a licensor of Arius \$1.0 million by August 24, 2004 pursuant to the terms of a license agreement between Arius and such licensor and (ii) fund, in a total amount of no less than \$2.0 million, the operations of Arius. The Company believes it has satisfied both of these conditions.

The terms of the Series A Preferred include a provision that if, at the time that any shares of Series A Preferred are converted, the Common Stock is listed for quotation on The Nasdaq SmallCap Market or The Nasdaq National Market, then, without the prior approval of the Company's stockholders in accordance with the rules of Nasdaq, the Company shall be prohibited from issuing shares of Common Stock to the extent that the total aggregate number of shares of Common Stock issued or deemed to be issued would exceed 19.99% of the issued and outstanding shares of Common Stock immediately prior to the effective time of the Arius acquisition. The purpose of this proposal is to obtain such stockholder approval.

*Nasdaq Listing Requirements and the Necessity of Stockholder Approval*

Neither Delaware law nor the Company's certificate of incorporation or the Company's bylaws required the Company to obtain stockholder approval in connection with the Arius acquisition or the issuance of the shares of Series A Preferred (or the shares of Common Stock thereunder) to the former stockholders of Arius. However, the Common Stock is listed on the Nasdaq SmallCap Market and, as such, the Company is subject to the NASD Marketplace Rules. Nasdaq Marketplace 4350(i)(1)(C)(ii) (the **Nasdaq 20% Rule**) requires that an issuer obtain stockholder approval in connection with the acquisition of the stock or assets of another company (i.e., Arius) if where, due to the present or potential issuance of common stock, or securities convertible into or exercisable for common stock, other than a public offering for cash: (a) the common stock has or will have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance of stock or

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securities convertible into or exercisable for common stock; or (2) the number of shares of common stock to be issued is or will be equal to or in excess of 20% of the number of shares or common stock outstanding before the issuance of the stock or securities. Shares of Common Stock issuable upon the exercise or conversion of the Series A Preferred are considered common stock issued for purposes of determining whether the 20% limit has been reached.



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As of August 24, 2004, there were 7,145,863 shares of Common Stock outstanding. Twenty percent of this number equals 1,429,173 shares. On a fully converted basis, based the one-for-one conversion rate of the Series A Preferred, the 1,647,059 shares of Series A Preferred issued to the former Arius stockholders would convert into 1,647,059 shares of Common Stock. Therefore, an aggregate of 217,886 shares of Common Stock (the **Series A Overage Shares** ) are potentially issuable in excess of that which is allowable under the Nasdaq 20% Rule. The Series A Preferred shares do not contain anti-dilution provisions (other than for stock splits and similar events), so the amount of Series A Overage Shares can be definitively calculated at this time.

### *Required Vote*

The affirmative vote of a majority of the issued and outstanding shares of the Common Stock entitled to vote thereon is necessary for approval of the issuance of the Series A Overage Shares. In connection with the acquisition of Arius, certain of Company stockholders, directors and officers (who, at the time, held in excess of 50% of the shares of outstanding Common Stock) agreed to vote all shares of Common Stock held by them at the Annual Meeting (and at each special or annual meeting of the Company thereafter until approval is gained) in favor of the issuance by the Company of all shares of Common Stock issuable upon conversion of all shares of the Series A Preferred which were issued in connection with the acquisition of Arius, including the Series A Overage Shares.

In the event the stockholders do not approve the potential issuance of Common Stock to the former stockholder of Arius, the Company will not issue Series A Overage Shares. The outcome of the vote of the Company's stockholders with respect to this Proposal No. 2 will not affect the acquisition of Arius. The acquisition of Arius was consummated August 24, 2004 and was not contingent on the Company's stockholders voting to approve the issuance of the Series A Overage Shares.

### *Recommendation of the Board of Directors*

**THE BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE FOR THE APPROVAL OF THE ISSUANCE OF THE SERIES A OVERAGE SHARES IN ACCORDANCE WITH THE NASDAQ 20% RULE.**

## **PROPOSAL 3**

### **APPROVAL OF CONVERSION TERMS OF THE COMPANY'S**

### **SERIES B CONVERTIBLE PREFERRED STOCK IN ACCORDANCE WITH**

### **NASDAQ MARKETPLACE RULE 4350(i)(1)(C)(ii)**

### *Background*

The purpose of Proposal 3 is to obtain the stockholder approvals necessary under applicable Nasdaq Stock Market rules to allow for the full conversion of shares of the Company's Series B Convertible Preferred Stock (the **Series B Preferred** ), aggregated with certain other of the Company's securities as described below.

*Summary*

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement (the **Equity Line Agreement**) with Hopkins Capital Group II, LLC ( **HCG** ), an affiliated entity of the Company which is controlled and partially-owned by Dr. Francis E. O'Donnell, Jr., the Company's Chairman and CEO.

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Pursuant to the Equity Line Agreement, HCG will, as requested by the Company, invest up to \$4,000,000 in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of Series B Preferred. In connection with the Company's acquisition of Arius on August 24, 2004, \$1.25 million was drawn under the Equity Line Agreement, and as of June 28, 2005, approximately \$1.45 million has been drawn under the Equity Line Agreement. The holders of the Series B Preferred will be entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred will be convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to \$4.25 per share. The Series B Preferred ranks senior to shares of Common Stock and the Series A Preferred shares and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

The terms of the Series B Preferred provide that, without the prior approval of the Company's stockholders, in no event shall the Company issue shares of Common Stock at any time upon conversion of the of: (i) the first \$1.25 million face value of Series B Preferred (representing 294,117 shares of Series B Preferred), plus (ii) any additional shares of Series B Preferred, the proceeds from the sale of which are used by the Company in connection with the acquisition Arius plus (iii) all shares of Series A Preferred (collectively, the **Aggregated Stock**) to the extent that the total aggregate number of shares of Common Stock issued or deemed to be issued at any time to any holder or all holders of the Aggregated Stock would exceed 19.99% of the issued and outstanding shares of Common Stock immediately prior to the effective time of the Company's acquisition of Arius. The purpose of this proposal is to obtain such stockholder approval.

### *Nasdaq Listing Requirements and the Necessity of Stockholder Approval*

The Common Stock is listed on the Nasdaq SmallCap Market and, as such, the Company is subject to the NASD Marketplace Rules. Shares of Common Stock issuable upon the exercise or conversion of the Series B Preferred are considered common stock issued for purposes of determining whether the 20% limit set forth in the Nasdaq 20% Rule has been reached.

At the time of the time of the acquisition of Arius, the NASD staff took the position that the Nasdaq 20% Rule was applicable to a portion of the Series B Preferred financing because certain (\$1.25 million) of the proceeds from the Series B Preferred financing were used in connection with the acquisition by the Company of Arius. As a result, an amount of Series B Preferred Shares was deemed to be aggregated with all of the Series A Preferred shares issued to the former Arius stockholders for purposes of compliance with the Nasdaq 20% Rule.

As of August 24, 2004, there were 7,145,863 shares of Common Stock outstanding. Twenty percent of this number equals 1,429,173 shares. On a fully converted basis, based the one-for-one conversion rate of the Series A Preferred, the 1,647,059 shares of Series A Preferred issued to the former Arius stockholders would convert into 1,647,059 shares of Common Stock. Further, based on the one-for-one conversion rate of the Series B Preferred, 294,117 shares of Series B Preferred (the proceeds of which were used in connection with the Arius acquisition) would convert into 294,117 shares of Common Stock. Therefore, the total amount of Aggregated Stock equals 1,941,176 shares of Common Stock and the difference between such shares of shares outstanding as of August 24, 2004 equals 512,003 (the **Series B Overage Shares**). It is this amount of shares of Common Stock that are potentially issuable in excess of that which is allowable under the Nasdaq 20% Rule. The Series B Preferred shares to not contain anti-dilution provisions (other than for stock splits and similar events), so the amount of Series B Overage Shares can be definitively calculated at this time.

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### *Required Vote*

The affirmative vote of a majority of the issued and outstanding shares of the Common Stock entitled to vote thereon is necessary for approval of the issuance of the Series B Overage Shares.

### *Recommendation of the Board of Directors*

**THE BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE FOR THE APPROVAL OF THE ISSUANCE OF THE SERIES B OVERAGE SHARES IN ACCORDANCE WITH THE NASDAQ 20% RULE.**

## **PROPOSAL 4**

### **APPROVAL OF CONVERSION TERMS OF THE COMPANY S FEBRUARY AND MAY 2005**

### **CONVERTIBLE NOTES AND WARRANTS AND JUNE 2005 WARRANTS ISSUED TO**

### **LAURUS MASTER FUND, LTD. IN ACCORDANCE WITH**

### **NASDAQ MARKETPLACE RULE 4350(i)(1)(D)(ii)**

### *Background*

The purpose of Proposal 4 is to obtain the stockholder approvals necessary under applicable Nasdaq Stock Market rules to allow for the full conversion of the February and May 2005 Convertible Notes (the **Notes** ) and Warrants (the **Warrants** ) and the two June 2005 Warrants (the **June Warrants** ) and, collectively with the Notes and the Warrants, the **Laurus Securities** ) issued by the Company to Laurus Master Fund, Ltd. ( **Laurus** ).

### *Summary*

#### *February 2005 Laurus Financing*

On February 22, 2005, the Company closed a \$2.5 million secured convertible debt financing from Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act of 1933, as amended. Net proceeds from the financing were used primarily to retire the Company s existing secured equipment loan with Gold Bank (on which approximately \$300,000 was owed) and to support the Company s research, development and commercialization opportunities and for general working capital purposes. The February Laurus investment, which took the form of a Note (the **February Note** ) secured by substantially all of the Company s assets, has a 3-year term and bears interest at a rate equal to prime plus 2% per annum. The February Note is convertible, under certain conditions, into shares of Common Stock at

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a price equal to \$3.10 per share. In connection with the financing, the Company also issued Laurus a Warrant (the **February Warrant** ), which allows Laurus to purchase up to 350,000 shares of Common Stock at a price equal to \$3.88 per share.

According to the terms of the February Note and the February Warrant, Laurus is not entitled to receive shares of Common Stock upon exercise of the February Warrant, upon payment of principal and interest on the February Note, or upon conversion of the February Note if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of the Common Stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to the Company). Further, in accordance with Nasdaq Stock Market rules, the aggregate number of shares of Common Stock issuable by the Company and acquirable by Laurus at an average price below \$3.10 per share pursuant to the terms of the February Note or the February Warrant, shall not exceed an aggregate of 1,428,458 shares of Common Stock (representing 19.99% of the Company's issued and outstanding shares of Common

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Stock on February 22, 2005, and subject to appropriate adjustment for stock splits, stock dividends, or other similar recapitalizations affecting the Common Stock (such issuance, the **Maximum Common Stock Issuance** ), unless the issuance of Common Stock in excess of the Maximum Common Stock Issuance (the **February Laurus Overage Amount** ) shall first be approved by the Company's stockholders.

### *May 2005 Laurus Financing*

Similarly, on May 31, 2005, the Company closed an additional \$2.5 million secured convertible debt financing from Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act of 1933, as amended. Net proceeds from the May financing were used primarily to support the Company's research, development and commercialization opportunities and for general working capital purposes. This Laurus investment also took the form of a Note (the **May Note** ) secured by substantially all of the Company's assets, which May Note has a 3-year term and bears interest at a rate equal to prime plus 2% per annum. As with the February Note, the May Note is convertible, under certain conditions, into shares of Common Stock at a price equal to \$3.10 per share. In connection with the May Laurus financing, the Company also issued Laurus a Warrant (the **May Warrant** ), which allows Laurus to purchase up to 483,871 shares of Common Stock at a price equal to \$3.88 per share.

According to the terms of the May Note and the May Warrant, Laurus is not entitled to receive shares upon exercise of the May Warrant, upon payment of principal and interest on the May Note, or upon conversion of the Note if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of the Common Stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to the Company). Further, in accordance with Nasdaq Stock Market rules, and pursuant to a position taken by the NASD staff, the aggregate number of shares of Common Stock issuable by the Company and acquirable by Laurus at an average price below \$3.10 per share pursuant to the terms of the Laurus Securities, aggregated together, shall not exceed an aggregate of 1,428,458 shares of Common Stock (representing 19.99% of the Company's issued and outstanding shares of common stock on February 22, 2005, and subject to appropriate adjustment for stock splits, stock dividends, or other similar recapitalizations affecting the common stock (such issuance the **May Maximum Common Stock Issuance** ), unless the issuance of Common Stock in excess of the May Maximum Common Stock Issuance (the **May Laurus Overage Amount** ) shall first be approved by the Company's stockholders.

### *June 2005 Amendments to Laurus Documents*

On June 29, 2005, the Company entered into two separate amendments to the Company's February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by the Company of principal under the February Note and the and May Note until December 1, 2005. In consideration of Laurus' agreement, the Company issued Laurus two warrants, one to purchase 22,500 shares of Common Stock (in connection with the February amendment) and a second to purchase 7,500 shares of Common Stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of Common Stock at an exercise price of \$.001 per share and expire on June 29, 2012. Except for the exercise price, the June Warrants issued to Laurus in connection with the foregoing amendments are substantially similar to the February Warrant and the May Warrant.

The shares of Common Stock underlying the June Warrants are deemed, for purposes of the Nasdaq 20% Financing Rule (as defined below), to be included in, respectively, the Maximum Common Stock Issuance and the May Maximum Common Stock Issuance.

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The purpose of this proposal is to obtain stockholder approval of the February Laurus Overage Amount and the May Laurus Overage Amount (which include, as the case may, the shares of Common Stock underlying the June Warrants).

### *Nasdaq Listing Requirements and the Necessity of Stockholder Approval*

The Common Stock is listed on the Nasdaq SmallCap Market and, as such, the Company is subject to the NASD Marketplace Rules. Nasdaq Marketplace Rule 4350(i)(1)(D)(ii) (the **Nasdaq 20% Financing Rule**) requires that an issuer obtain stockholder approval prior to the issuances of common stock or securities convertible into or exchangeable for common stock at a price equal to or less than the greater of market or book value of such securities (on an as-converted basis) if such issuance equals 20% or more of the common stock or voting power of the issuer outstanding before the transaction. Shares of Common Stock issuable upon the exercise or conversion of the Laurus Securities are considered common stock issued for purposes of determining whether the 20% limit has been reached.

The June Warrants are exercisable into shares of Common Stock at \$.001 per share. Therefore, when aggregated with the other Laurus Securities as required by the Nasdaq Stock Market, such shares of Common Stock require stockholder approval under the Nasdaq 20% Financing Rule. In addition, although the Common Stock issuable upon the exercise or conversion of the other Laurus Securities will initially have been issued at (or at a premium to) the market prices on the initial closing date of the February Laurus financing, the conversion price of the Notes and the exercise price of the Warrants may adjust downward if the Company issues securities (subject to certain exceptions) below the conversion or exercise price of such securities. If adjustments to the conversion price of the Notes and/or exercise price of the Warrants take place, the underlying shares of Common Stock issuable upon conversion and exercise thereof may be deemed to have been issued below the market price of the Common Stock on the closing date of the February Laurus Financing. Because of these potential adjustments, and because of the position of the NASD staff to aggregate the February and May Laurus financings (as well as shares of Common Stock underlying the June Warrants), the Company is seeking stockholder approval of the February Laurus Overage Amount and the May Laurus Overage Amount in order to comply with the Nasdaq 20% Financing Rule.

### *Required Vote*

The affirmative vote of a majority of the issued and outstanding shares of the Common Stock entitled to vote thereon is necessary for approval of the issuance of the February Laurus Overage Amount and the May Laurus Overage Amount.

If this proposal is not approved by stockholders, the May Note, which is structured as a three year note, will become due and owing on September 1, 2005. At such time, Laurus may require the Company satisfy all of its obligations under the May Note, including the payment in full of all principal and interest and may pursue other legal or equitable remedies against the Company. The Company's ability to make such cash payments will depend on its available cash resources at that time, and there can be no assurance that the Company will have the cash necessary to make such payments. The early payment of the May Note may thus adversely affect the liquidity and financial condition of the Company.

### *Recommendation of the Board of Directors*

**THE BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE FOR THE APPROVAL OF THE ISSUANCE OF THE FEBRUARY LAURUS OVERAGE AMOUNT AND THE MAY LAURUS OVERAGE AMOUNT IN ACCORDANCE WITH THE NASDAQ 20% FINANCING RULE.**





**Table of Contents****PROPOSAL 5****RATIFICATION OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY****AS THE COMPANY'S INDEPENDENT AUDITORS FOR FISCAL 2005**

On January 27, 2005 the audit committee of the Board of Directors appointed the firm of Aidman, Piser & Company, P.A. ( **AP** ) to serve as the Company's independent auditors for the Company's fiscal year ended December 31, 2005.

The independent accountant's report of AP on the Company's consolidated financial statements for the year ended December 31, 2004 contained no adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles.

The following fees were incurred by the Company for the services of AP in fiscal 2004 and fiscal 2003.

|                    | <u>2004</u> | <u>2003</u> |
|--------------------|-------------|-------------|
| Audit Fees         | \$ 85,000   | \$ 37,426   |
| Audit-Related Fees | \$ 34,025   | \$ 26,700   |
| Tax Fees           | \$ 17,600   | \$ 10,000   |
| All Other Fees     | \$ 0        | \$ 0        |

*Audit Fees.* The aggregate fees billed by AP for professional services rendered for the audit of the Company's annual financial statements for the years ended December 31, 2004 and 2003, the review of the financial statements included in the Company's Forms 10-QSB and consents issued in connection with a subsidiary's registration statement filings for 2003 totaled, respectively, \$85,000 and \$37,426. Interim procedures are included as audit fees as well as attendance at audit committee meetings.

*Audit-Related Fees.* The aggregate fees billed by AP for audit-related fees for the years ended December 31, 2004 and 2003 were \$34,025 and \$26,700, respectively. Audit-related fees in 2003 were related to a subsidiary registration statements and amendments thereto filed with the SEC.

*Tax Fees.* The aggregate fees billed by AP for professional services rendered for tax compliance, for the years ended December 31, 2004 and 2003, were \$17,600 and \$10,000, respectively.

*All Other Fees.* The aggregate fees billed by AP for products and services, other than the services described in the paragraphs captions "Audit Fees", and "Tax Fees" above for the years ended December 31, 2004 and 2003 totaled none for both years.

The Audit Committee of the Company's Board of Directors has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the foregoing audit, tax and non-audit services provided by AP in 2004. Consistent with the Audit Committee's responsibility for engaging the Company's independent auditors, all audit and permitted non-audit services require pre-approval by the Audit

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Committee. The full Audit Committee approves proposed services and fee estimates for these services. The Audit Committee chairperson or their designee has been designated by the Audit Committee to approve any services arising during the year that were not pre-approved by the Audit Committee. Services approved by the Audit Committee chairperson are communicated to the full Audit Committee at its next regular meeting and the Audit Committee reviews services and fees for the fiscal year at each such meeting. Pursuant to these procedures, the Audit Committee approved the foregoing audit services provided by AP.

A representative of AP is expected to attend the Meeting.

**THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE APPROVAL OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY, P.A. AS THE COMPANY'S INDEPENDENT AUDITORS FOR THE FISCAL YEAR ENDED DECEMBER 31, 2005.**

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**OTHER INFORMATION**

**Proxy Solicitation**

All costs of solicitation of proxies will be borne by the Company. In addition to solicitation by mail, the Company's officers and regular employees may solicit proxies personally or by telephone. The Company does not intend to utilize a paid solicitation agent.

**Proxies**

A stockholder may revoke his, her or its proxy at any time prior to its use by giving written notice to the Secretary of the Company, by executing a revised proxy at a later date or by attending the Meeting and voting in person. Proxies in the form enclosed, unless previously revoked, will be voted at the Meeting in accordance with the specifications made thereon or, in the absence of such specifications in accordance with the recommendations of the Company's Board of Directors.

**Securities Outstanding; Votes Required**

As of the close of business on the Record Date (June 28, 2005), there were 7,269,196 shares of Common Stock outstanding, 1,647,059 shares of the Series A Preferred outstanding and 341,176 shares of the Series B Preferred outstanding. Stockholders are entitled to one vote for each share of Common Stock owned. The holders of Series A Preferred and Series B Preferred have no voting right with respect to such securities. The affirmative vote of a majority of the shares of Common Stock present at the Meeting, in person or by proxy, is required for approval of the proposals. Shares of the Common Stock represented by executed proxies received by the Company will be counted for purposes of establishing a quorum at the Meeting, regardless of how or whether such shares are voted on any specific proposal.

**Other Business**

The Company's Board of Directors knows of no other matter to be presented at the Meeting. If any additional matter should properly come before the meeting, it is the intention of the persons named in the enclosed proxy to vote such proxy in accordance with their judgment on any such matters.

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**Table of Contents****Beneficial Ownership of Principal Stockholders, Officers and Directors**

The following table sets forth, as of June 28, 2005, certain information as to the stock ownership of each person known by the Company to own beneficially 5% or more of the outstanding Common Stock, of each of the Company's named officers and directors who owns any shares and of all officers and directors as a group. In computing the outstanding shares of Common Stock, the Company has excluded all shares of Common Stock subject to options or warrants that are not currently exercisable or exercisable within 60 days and are therefore not deemed to be outstanding and beneficially owned by the person holding the options or warrants for the purpose of computing the number of shares beneficially owned and the percentage ownership of that person.

| Name of Beneficial Owner  | Number of Shares<br>of Common Stock<br>Owned <sup>(1)</sup> | Percentage of<br>Class as of<br>June 28, 2005 |
|---|---|---|
| Hopkins Capital Group II, LLC <sup>(2)</sup>                      | 3,111,580   | 42.8%   |
| Francis E. O'Donnell, Jr., M.D. <sup>(3)</sup>                    | 3,492,113   | 48.0%   |
| The Francis E. O'Donnell, Jr. Irrevocable Trust #1 <sup>(4)</sup> | 3,279,080   | 45.1%   |
| Pharmaceutical Product Development, Inc. <sup>(5)</sup>           | 690,000   | 9.5%  |
| Jonnie R. Williams, Sr. <sup>(6)</sup>                            | 3,203,114   | 44.1%   |
| MOAB Investments, LP <sup>(7)</sup>                               | 3,157,347   | 43.4%   |
| Mark A. Sirgo, Pharm.D. <sup>(8)</sup>                            | 6,000   | *   |
| Andrew L. Finn, Pharm.D. <sup>(9)</sup>                           |   | *   |
| Raphael J. Mannino, Ph.D. <sup>(10)</sup>                         | 397,025   | 5.5%  |
| James A. McNulty <sup>(11)</sup>                                  | 82,865  | 1.1%  |
| Donald L. Ferguson <sup>(12)</sup>                                | 274,600   | 3.8%  |
| L.M. Stephenson, Ph.D. <sup>(13)</sup>                            | 85,000  | 1.2%  |
| William B. Stone <sup>(14)</sup>                                  | 140,000   | 1.9%  |
| John J. Shea <sup>(15)</sup>                                      | 70,000  | 1.0%  |
| William S. Poole <sup>(16)</sup>                                  |   | *   |
| Alan Pearce <sup>(17)</sup>                                       | 85,000  | 1.2%  |
| All Directors and Officers as a group (11 persons)                | 4,707,603   | 64.8  |

\* Less than 1%

(1) Based on 7,269,196 shares of common stock outstanding as of June 28, 2005.

(2) Hopkins Capital Group II, LLC is owned one third by each of: (i) various trusts of the O'Donnell family (see Note 4); (ii) John R. Williams, Sr. and his family trusts (see Note 6); and (iii) MOAB Investments, LP, which is beneficially owned by Dr. Dennis Ryll and members of his family (see Note 7). Hopkins Capital Group II, LLC also owns 341,176 shares of the Company's Series B Convertible Preferred Stock, of which none are presently convertible into shares of Common Stock.

(3) Dr. O'Donnell is the Chief Executive Officer, Chairman of the Board and a Director of the Company. Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2) and 45,767 shares of common stock, owned by his wife, as to which Dr. O'Donnell disclaims beneficial interest of. Excludes 167,000 shares owned by The Francis E. O'Donnell, Jr. Irrevocable Trust #1, of which Dr. O'Donnell's sister, Kathleen O'Donnell, is trustee, and as to which Dr. O'Donnell disclaims beneficial interest (see Note 4). The remaining 4,576 shares of common stock are owned by Dr. O'Donnell's sister. In addition, this number includes options to purchase 105,000 shares of Common Stock, all of which is currently exercisable. Dr. O'Donnell's address is 709 The Hampton Lane, Chesterfield MO 63017.

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- (4) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2), of which The Francis E. O. Donnell, Jr. Irrevocable Trust #1 owns approximately 27%. The remaining 167,500 shares of common stock are held directly by this trust.
  
- (5) PPDI s address is 3151 South Seventeenth Street, Wilmington, NC 28412.

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- (6) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). Also includes 45,766 shares of common stock that are personally owned by Mr. Williams and an additional 45,767 shares owned by Mr. Williams's wife. Mr. Williams's address is 1 Starwood Lane, Manakin-Sabot, VA 23103.
- (7) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). MOAB Investments, LP is beneficially owned by Dr. Dennis Ryll and members of his family. The remaining 45,767 shares of common stock are personally owned by Dr. Ryll. The address for MOAB and Dr. Ryll is 2595 Red Springs Drive, Las Vegas, NV 89135.
- (8) Includes 6,000 shares owned by Dr. Sirgo, the President and Chief Operating Officer of the Company. Dr. Sirgo also owns 797,414 shares of the Company's Series A Convertible Preferred Stock, of which none are presently convertible into shares of Common Stock. Dr. Sirgo's address is 3100 Stone Gap Court Raleigh, North Carolina 27612.
- (9) Dr. Finn is the Executive Vice President and Chief Operating Officer of the Company. Dr. Finn owns 797,414 shares of the Company's Series A Convertible Preferred Stock, of which none are presently convertible into shares of Common Stock. Dr. Finn's address is 737 West Hargett Street, Raleigh, NC 27603.
- (10) Dr. Mannino is the Executive Vice President, Chief Scientific Officer and a Director of the Company. Includes options to purchase 242,016 shares of Common Stock, all of which are currently exercisable.
- (11) Mr. McNulty is the Chief Financial Officer, Secretary and Treasurer of the Company. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. His address is 4419 W. Sevilla Street, Tampa, FL 33629.
- (12) Mr. Ferguson is the Senior Executive Vice President of the Company. Includes options to purchase 274,600 shares of Common Stock, all of which are currently exercisable. Mr. Ferguson's address is 11477 Olde Cabin Road, Suite 110, St. Louis, MO 63141.
- (13) Includes options to purchase 55,000 shares of Common Stock, all of which are currently exercisable. Dr. Stephenson's address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.
- (14) Includes options to purchase 105,000 shares of Common Stock, all of which are currently exercisable. Mr. Stone's address is 11120 Geyer Downs Lane, Frontenac, MO 63131.
- (15) Includes options to purchase 60,000 shares of Common Stock, all of which are currently exercisable. Mr. Shea's address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.
- (16) Mr. Poole owns 3,190 shares of the Company's Series A Convertible Preferred Stock, of which none are presently convertible into shares of Common Stock. Mr. Poole's address is 1301 Kings Grant Drive, Raleigh, NC 27614.
- (17) Includes options to purchase 60,000 shares of Common Stock, all of which are currently exercisable. Mr. Pearce's address is 35 Watergate Drive, #706, Sarasota, FL 34236.

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**Deadline for Submission of Stockholder Proposals for 2006 Annual Meeting of Stockholders**

Stockholders may present proposals for inclusion in the Proxy Statement for the 2006 Annual Meeting of Stockholders provided that such proposals are received by the Secretary of the Company in accordance with the time schedules set forth in, and otherwise in compliance with, applicable SEC regulations. Proposals submitted not in accordance with such regulations will be deemed untimely or otherwise deficient, however, the Company will have discretionary authority to include such proposals in the 2006 Proxy Statement.

**Stockholder Communications**

Stockholders wishing to communicate with the Board of Directors may direct such communications to the Board of Directors c/o the Company, Attn: James A. McNulty. Mr. McNulty will present a summary of all stockholder communications to the Board of Directors at subsequent Board of Directors meetings. The directors will have the opportunity to review the actual communications at their discretion.

**Additional Information**

Accompanying this Proxy Statement is a copy of the Company's 2004 Annual Report to Stockholders, which includes the Company's Annual Report on Form 10-KSB/A for the year ended December 31, 2004. Such Report constitutes the Company's Annual Report to its Stockholders for purposes of Rule 14a-3 under the Securities Exchange Act of 1934. Such Report includes the Company's audited financial statements for the 2002 fiscal year and certain other financial information, which is incorporated by reference herein.

The Company is subject to the informational requirements of the Securities Exchange Act of 1934 and in accordance therewith files reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information are available for inspection and copying at the public reference facilities maintained by the SEC at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, DC 20549, and on the SEC's website at [www.sec.gov](http://www.sec.gov). Copies of such materials may be obtained upon payment of the SEC's customary charges by writing to the Public Reference Section of the SEC at Judiciary Plaza, 450 Fifth Street, N.W., Washington, DC 20549.

Stockholders who have questions in regard to any aspect of the matters discussed in this Proxy Statement should contact James McNulty, Chief Financial Officer of the Company, at (813) 864-2562.

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**Proxy**

**BioDelivery Sciences International, Inc.**

**2501 Aerial Center Parkway, Suite 205**

**Morrisville, NC 27560**

**THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS**

THE UNDERSIGNED HEREBY APPOINTS FRANCIS E. O DONNELL, JR. AND JAMES A. MCNULTY, AND EACH OF THEM, AS PROXIES OF THE UNDERSIGNED, WITH FULL POWER OF SUBSTITUTION, TO VOTE ALL THE SHARES OF COMMON STOCK OF BIODELIVERY SCIENCES INTERNATIONAL, INC. HELD OF RECORD BY THE UNDERSIGNED ON JUNE 28, 2005, AT THE ANNUAL MEETING OF SHAREHOLDERS TO BE HELD ON THURSDAY, JULY 28, 2005, OR ANY ADJOURNMENT THEREOF.

1. To elect seven directors to serve until the 2006 annual meeting of the shareholders.

.. FOR all nominees listed (except as marked to the contrary below)

.. WITHHOLD AUTHORITY to vote for all nominees listed below

Francis E. O Donnell, Jr.

Raphael J. Mannino

William B. Stone

John J. Shea

L.M. Stephenson

Alan Pearce

William S. Poole

**(Instruction: To withhold authority to vote for any individual nominee, place a line through the nominee's name.)**



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2. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii), the conversion terms of the Company's Series A Non-Voting Convertible Preferred Stock to the extent that the shares of Common Stock issuable upon conversion of such Series A Convertible Preferred Stock could potentially equate to 20% or more of Common Stock outstanding as of August 24, 2004, the date of issuance;

“ FOR

“ AGAINST

“ ABSTAIN

3. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(C)(ii), the conversion terms of the Company's Series B Convertible Preferred Stock to the extent that the shares of Common Stock issuable upon conversion of the first \$1.25 million of such Series B Convertible Preferred Stock, when aggregated with the shares of Common Stock underlying all shares of the Company's Series A Non-Voting Convertible Preferred Stock, could potentially equate to 20% or more of Common Stock outstanding as of August 24, 2004, the deemed date of issuance;

“ FOR

“ AGAINST

“ ABSTAIN

4. To approve and ratify, in accordance with Nasdaq Marketplace Rule 4350(i)(1)(D)(ii), the conversion terms of the Company's February and May 2005 Convertible Notes and Warrants and June 2005 Warrants issued to Laurus Master Fund, Ltd. to the extent that the shares of Common Stock issuable upon conversion of such securities could potentially equate to 20% or more of Common Stock outstanding as of February 22, 2005, the deemed date of issuance;

“ FOR

“ AGAINST

“ ABSTAIN

5. 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, 2005; and

“ FOR

“ AGAINST

“ ABSTAIN

6. In their discretion, upon the transaction of any other matters which may properly come before the meeting or any adjournment thereof.

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The shares represented by this proxy, when properly executed, will be voted as specified by the undersigned shareholder(s). If this card contains no specific voting instructions, the shares will be voted **FOR** each of the proposals described on this card.

**Signature(s) of Stockholder(s)**

**Dated** \_\_\_\_\_, 2005

Please sign exactly as the name appears below. When shares are held by joint tenants, both should sign. When signing as attorney, executor, administrator, trustee or guardian, please give full title as such. If a corporation, please sign the corporate name by the president or other authorized officer. If a partnership, please sign in the partnership name by an authorized person.