

BIODELIVERY SCIENCES INTERNATIONAL INC

Form DEF 14A

June 27, 2006

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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.**

(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):

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x No fee required.

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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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.. 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 28, 2006

To the Stockholders of BioDelivery Sciences International, Inc.:

BioDelivery Sciences International, Inc. (the **Company**) is pleased to send you the enclosed notice of the 2006 Annual Meeting of Stockholders of the Company (the **Meeting**) to be held at 11:00 a.m. on Thursday, July 27, 2006 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 June 28, 2006.

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

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

Sincerely yours,

Francis E. O' Donnell, Jr.  
Chairman of the Board of Directors  
BioDelivery Sciences International, Inc.

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

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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 27, 2006**

The 2006 Annual Meeting of Stockholders (the **Meeting**) of BioDelivery Sciences International, Inc. (the **Company**) will be held at 11:00 a.m. on Thursday, July 27, 2006, 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 2007 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
2. To approve an amendment to the Company's Amended and Restated 2001 Incentive Plan to increase the number of shares of common stock reserved for issuance under such plan from 2,100,000 to 3,500,000;
3. To approve and ratify the terms of the issuance by the Company of 2,000,000 shares of Company common stock and a warrant to purchase 904,000 shares common stock issued to CDC IV, LLC on May 16, 2006 (aggregated with a previously warrant to purchase 601,120 shares of common stock issued to CDC IV, LLC on July 15, 2005) in accordance with Nasdaq Marketplace Rule 4350(i)(1)(D)(ii);
4. 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, 2006; and
5. To transact such other business as may properly come before the meeting or any adjournment thereof.

Stockholders are cordially invited to attend the Meeting in person. **However, to assure your representation at the Meeting, please complete and sign the enclosed proxy card and return it promptly.** Even if you have previously submitted a proxy card you may choose to vote in person at the Meeting. Whether or not you expect to attend the Meeting, please read the attached proxy statement and then promptly complete, date, sign and return the enclosed proxy card in order to ensure your representation at the Meeting.

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

BY ORDER OF THE BOARD OF DIRECTORS

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

Morrisville, North Carolina

June 28, 2006

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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 27, 2006, 11:00 a.m.**

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

**1500 RDU Center Drive**

**Morrisville, NC 27560**

**INTRODUCTION**

*2006 Annual Meeting of Stockholders*

This Proxy Statement is being furnished to holders of shares of common stock, \$.001 par value (the **Common Stock**) of BioDelivery Sciences International, Inc., a Delaware corporation (the **Company**), in connection with the solicitation of proxies by the board of directors of the Company (the **Board of Directors**) for use at the 2006 Annual Meeting of Stockholders of the Company (the **Meeting**). The Meeting is to be held at 11:00 a.m. on Thursday, July 27, 2006 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 23, 2006 (the **Record Date**) as the record date for the determination of stockholders entitled to notice of, and to vote and act at, the Meeting. Only stockholders of record at the close of business on that date are entitled to notice of, and to vote and act at, the Meeting. The Proxy Statement is first being mailed to stockholders of the Company on or about June 28, 2006.

*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 2007 Annual Meeting of Stockholders or until their successors are duly elected and qualified;
2. To approve an amendment to the Company's Amended and Restated 2001 Incentive Plan to increase the number of shares of common stock reserved for issuance under such plan from 2,100,000 to 3,500,000;

3. To approve and ratify the terms of the issuance by the Company of 2,000,000 shares of Common Stock and a warrant to purchase 904,000 shares of Common Stock



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issued to CDC IV, LLC on May 16, 2006 (aggregated with a previously warrant to purchase 601,120 shares of Common Stock issued to CDC IV, LLC on July 15, 2005) to the extent that the shares of Common Stock issuable upon issuance and exercise of such warrants could potentially equate to twenty (20%) percent or more of Common Stock outstanding as of May 16, 2006, the deemed date of issuance;

4. 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, 2006; and
5. 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 13,938,146 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 and 4.

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,

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by an officer or attorney thereof duly authorized, and deposited either at the corporate headquarters of the Company at any time up to and including the last business day preceding the day of the Annual Meeting, or any adjournments thereof, at which the proxy is to be used, or with the chairman of such Annual Meeting on the day of the Annual Meeting or adjournments thereof, and upon either of such deposits the proxy is revoked.

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

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

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**PROPOSAL 1**

**ELECTION OF DIRECTORS**

*Introduction*

The Board of Directors currently consists of one class of directors having seven (7) members. The Board of Directors may determine the total number of directors and the number of directors to be elected at any annual meeting or special meeting in lieu thereof. The Board of Directors has fixed at seven (7) the number of directors to be elected at the Meeting. At the Meeting, stockholders will be asked to elect Francis E. O'Donnell, Jr., Mark A. Sirgo, Raphael J. Mannino, L.M. Stephenson, William B. Stone, John J. Shea and William S. Poole (the **Nominees**) to serve in such capacity until the 2007 Annual Meeting, or until their successors are duly elected and qualified.

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

*Directors and Executive Officers*

Listed below are the names of the directors, executive officers and significant employees of the Company, their ages as of June 28, 2006 and positions held:

| <b>Name</b>                     | <b>Age</b> | <b>Position</b>   |
|---------------------------------|------------|---|
| Francis E. O'Donnell, Jr., M.D. | 56         | Chairman of the Board and Director                                      |
| Mark A. Sirgo, Pharm.D.         | 52         | President, Chief Executive Officer and Director                         |
| Raphael J. Mannino, Ph.D.       | 59         | Executive Vice President, Chief Scientific Officer and Director         |
| Andrew L. Finn, Pharm.D.        | 57         | Executive Vice President of Clinical Development and Regulatory Affairs |
| Mark W. Salyer                  | 47         | Executive Vice President of Sales and Marketing                         |
| James A. McNulty                | 55         | Chief Financial Officer, Secretary and Treasurer                        |
| L.M. Stephenson, Ph.D.          | 64         | Director  |
| William B. Stone                | 63         | Director  |
| John J. Shea                    | 79         | Director  |
| William S. Poole                | 59         | Director  |

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

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

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*Francis E. O' Donnell, Jr., M.D.*, age 56, is the Chairman of the Board and has been a Director of the Company since March 29, 2002. Dr. O' Donnell has previously served as President and Chief Executive Officer of the Company. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. For more than the last six years, Dr. O' Donnell has served as managing director of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. He is a co-founder and chairman of RetinaPharma Technologies, Inc. which now includes Tatton Technologies, LLC, and a co-founder of Biotech Specialty Partners, LLC, an alliance of specialty pharmaceutical and biotechnology companies. He serves as Chairman and CEO of Accentia 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 52, was appointed President and Chief Executive Officer of the Company in July 2005. This followed his appointment as President and Chief Operating Officer of the Company in January 2005. He joined the Company in August 2004 upon the acquisition of Arius Pharmaceuticals, Inc., 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 59, 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 57, 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 Company's acquisition of Arius Pharmaceuticals, Inc., 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

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responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for 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.

*Mark W. Salyer*, age 47, has served as the Company's Executive Vice-President of Sales and Marketing since January 2006. From 2002 until the time he joined the Company, Mr. Salyer served in a dual role as Senior Vice-President, Sales and Marketing for the U.S. and Corporate Vice-President, Global Franchise Management-Respiratory for Altana Pharma AG. Prior to joining Altana, Mr. Salyer spent 17 years at GlaxoSmithKline in numerous leadership roles including Vice President, Global Commercial Strategy for Respiratory Products based in London, England; Director of Marketing for Respiratory and Migraine Brands in the U.S., and other strategic and financial roles. Mr. Salyer holds CPA licenses in North Carolina and Virginia, a BS in Accounting from Virginia Tech and a MBA from Duke University's Fuqua School of Business. Mr. Salyer is an active member of the Healthcare Advisory Board of Duke University's Fuqua School of Business.

*James A. McNulty*, age 55, 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 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.

*L.M. Stephenson, Ph.D.*, age 64, is a member of the Board of Directors. From 2003 until March 2006, Dr. Stephenson served as 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

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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 63, 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 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 79, 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 59, is a member of the Board of Directors. He has extensive experience in the biopharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. He later served as President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, and also as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building a solid management team and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly oversaw vice presidents in charge of manufacturing, research & development, sales, legal, marketing, finance, regulatory and human resources functions. In recent years, Mr. Poole has acted as a private consultant and, until his appointment to the board, Mr. Poole served as a member of the Commercial Advisory Board of BDSI's subsidiary, Arius Pharmaceuticals.

*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 ( **HCG** ), which is controlled by Dr. Francis E. O'Donnell, Jr., the Company's Chairman 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 Accentia. In addition, Dr. O'Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, the Company's Secretary, Treasurer and CFO, is the Secretary and Treasurer of Accentia, and Dr. Raphael J. Mannino, the Company's Executive Vice President and Chief Scientific Officer, is a director of Biovest International, Inc. (OTC BB:BVTI), a subsidiary of Accentia.

*Amphotericin B License.* On April 12, 2004, the Company licensed a topical formulation of its encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation 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 shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

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*Arius/TEAMM Distribution Agreement.* On March 17, 2004, the Company's Arius Pharmaceuticals, Inc. subsidiary ( **Arius** ) granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., with respect to the Company's 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 and an additional \$300,000 in 2005 upon the acceptance of the Emezine™ New Drug Application for filing.

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

Mr. James A. McNulty, the Company's Secretary, Treasurer and part-time Chief Financial Officer, is also the Chief Financial Officer of HCG, which is affiliated with Dr. Francis E. O'Donnell, Jr., the Company's Chairman of the Board.

During 2001, the Company entered into agreements with RetinaPharma, Inc. (now called RetinaPharma Technologies, Inc.) and Tatton Technologies, LLC (now a part of RetinaPharma). Both are biotechnology companies which are developing nutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson's disease. To the extent that such drugs utilize 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. HCG, one of the Company's significant stockholders, and Dr. Francis E. O'Donnell, Jr., the Chairman of the Board and a director, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O'Donnell is the managing director of HCG.

The Company has also entered into an agreement with Biotech Specialty Partners, LLC, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. Biotech Specialty Partners, LLC is in its formative stage and to date has not distributed any pharmaceutical products. Under this agreement, BSP will serve as a nonexclusive distributor of the Company's Bioral® drugs in consideration of a ten (10%) discount to the wholesale price, which the Company's 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, which is affiliated with Dr. Francis E. O'Donnell, Jr., the Company's Chairman of the Board and a director, are affiliated as stockholders, and a member of the management, of Biotech Specialty Partners, LLC.

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On July 19, 2002, the Company issued Ellenoff Grossman & Schole LLP, the Company's 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 of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

As a matter of corporate governance policy, 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 the Company's 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 which constitute a majority as required by NASD rules. The Company believes that William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole qualify as independent directors for Nasdaq Stock Market purposes.

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 Company's 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 and other than with respect to the ownership of the Company's Series A Stock and Series B Stock by certain of our management and HCG, respectively, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which the Company were or are to be a party, in which the amount involved exceeds \$60,000, and in which any director or executive officer, or any security holder who is known by the Company to own of record or beneficially more than 5% of any class of 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*

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



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16(a) reports and representations received by the Company from reporting persons, and without conducting any independent investigation, in 2005, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

### *Meetings of the Board of Directors*

The Board of Directors met in person and telephonically nine times during 2005 and also acted by unanimous written consent. It is the Company's policy that all directors must attend all meetings, barring extenuating circumstances. All Nominees were present at seventy-five (75%) percent or more of the Board of Directors meetings held during such director's tenure as a member of the Board of Directors.

### *Director Independence*

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.

On September 15, 2005, the Company received a written deficiency notification from the staff of the Nasdaq Stock Market indicating the staff's view that Donald L. Ferguson was not independent under NASD Rule 4200(a)(15) and that, therefore, the Board of Directors was not composed of a majority of independent directors as required by NASD Rule 4350(c)(1). Accordingly, the NASD staff indicated its position that the Company did not meet the independent director requirement for continued listing on the Nasdaq Stock Market.

As a result of the NASD staff's determination, Mr. Ferguson and Alan Pearce, a director of the Company who was not independent, resigned from the Board of Directors effective September 15, 2005. The Company notified the NASD staff of this action and, as a result, the staff provided us with a written notification that the Company had regained compliance with NASD rules and that this matter is closed.

### *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.

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

### *Audit Committee*

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 six times during 2005. 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

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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 Company's 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 the unaudited financial statements to be included in the Company's Quarterly Reports on Form 10-QSB and reviews with management and the independent auditors the results of the annual audit and quarterly reviews. In addition, the Audit Committee oversees all aspects of the Company's systems of internal accounting control and corporate governance functions on behalf of the Board of Directors. The Audit Committee provides oversight in connection with legal and ethical compliance programs established by management and the Board of Directors, 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 S. Poole, L.M. Stephenson and John J. Shea. Mr. Shea serves as the chairman of the committee. Mr. Shea was named chairman of this committee on August 22, 2005. 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 2004 and did not meet formally in 2005, although members of the committee were involved with interviews of William S. Poole prior to his joining the Board of Directors in April 2005. The Nominating and Corporate Governance Committee has a charter. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASD. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o the Company, Attn: James A McNulty. There are no minimum qualifications for consideration for nomination to be a director of the Company. The nominating committee will assess all director nominees using the same criteria. All of the current nominees to serve as directors on the Board of Directors have previously served in such capacity. During 2005, the Company did not pay any fees to any third parties to assist in the identification of nominees. During 2005, 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 of Directors, as the case may be, reviews or recommends the compensation arrangements for the Company's management. The members of the compensation committee are William S. Poole, who was named chairman of this committee effective August 22, 2005 (replacing Dr. O'Donnell), L.M. Stephenson and William B. Stone. The compensation committee met one time during 2005. The Board of Directors also has an investment committee, which either alone or in conjunction with the full Board of Directors, 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 and L.M. Stephenson. The investment committee as such did not meet during 2005.

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, 2005. 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

\* 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><b>Name and<br/>Principal Position</b>  | (b)<br><b>Year</b> | Long Term Compensation                                       |                              |  | (f)<br><b>Restricted<br/>Stock<br/>Award(s)<br/>(\$)</b> | (g)<br><b>Awards<br/>Securities<br/>Underlying<br/>Options/SARs<br/>(#)</b> | Payouts                                 |   |
|--|--------------------|--|------------------------------|--|--|---|---|---|
|  |                    | (c)<br><b>Annual<br/>Compensation<sup>(1)</sup><br/>(\$)</b> | (d)<br><b>Bonus<br/>(\$)</b> | (e)<br><b>Other<br/>Annual<br/>Compensation<br/>(\$)</b> |  |   | (h)<br><b>LTIP<br/>Payouts<br/>(\$)</b> | (i)<br><b>All Other<br/>Compensation<br/>(\$)</b> |
|  |                    |  |                              |  |  |   |   |   |
| Francis E. O'Donnell, Jr., M.D.<br>Chairman and Director<br>709 The Hampton Lane<br>Chesterfield, MO 63017   | 2005               | \$ 0   |                              |  |  | 25,000  |   |   |
|  | 2004               | 117,692  |                              |  |  | 35,000  |   |   |
|  | 2003               | 145,962  |                              |  |  | 35,000  |   |   |
| Mark A. Sirgo, Pharm.D.,<br>President and Chief Executive Officer<br>3100 Stone Gap Court<br>Raleigh, North Carolina 27612   | 2005               | \$ 202,366   |                              |  |  | 77,929  |   |   |
|  | 2004               | 62,596   | 31,177                       |  |  | 5,147   |   |   |
|  | 2003               |  |                              |  |  |   |   |   |
| Andrew L. Finn, Pharm.D.,<br>Executive Vice President of Clinical<br>Development<br>and Regulatory Affairs<br>737 West Hargett Street<br>Raleigh, NC 27603   | 2005               | \$ 192,471   |                              |  |  | 57,929  |   |   |
|  | 2004               | 62,596   | 28,092                       |  |  | 5,147   |   |   |
|  | 2003               |  |                              |  |  |   |   |   |
| James A. McNulty,<br>Chief Financial Officer, Secretary and<br>Treasurer<br>4419 W. Sevilla Street<br>Tampa, FL 33629  | 2005               | \$ 113,670   |                              |  |  | 36,189  |   |   |
|  | 2004               | 105,866  | \$                           |  |  | 3,235   |   |   |
|  | 2003               | 141,769  |                              |  |  | 18,616  |   |   |
| Raphael J. Mannino, Ph.D. <sup>(2)</sup> ,<br>Executive Vice President and Chief<br>Scientific Officer<br>UMDNJ New Jersey Medical School<br>185 South Orange Avenue, Building 4<br>Newark, NJ 07103 | 2005               | \$ 97,171  |                              | 11,250   |  | 30,714  |   | \$ 3,543  |
|  | 2004               | 88,788   |                              | 11,423   |  | 26,176  |   | 5,015   |
|  | 2003               | 90,000   | 52,500                       |  |  | 111,449   |   | 5,015   |

\* 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)

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Includes: (a) a car allowance of \$6,750 and 401(k) matching of \$4,500 paid in 2005 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). Excludes \$114,690, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2005 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

**Table of Contents***Option Grants During Year Ended December 31, 2005*

| (a)                       | Individual Grants                                       |   | (d)                            | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term |           |            |
|---------------------------|---|---|--------------------------------|--|-----------|------------|
|                           | (b)   | (c)   |                                | (e)  | (f)       | (g)        |
| Name                      | Number of Securities Underlying Options/SARs Granted(#) | Percent of Total Options/SARs Granted to Employees in Fiscal Year | Exercise or Base Price (\$/Sh) | Expiration Date  | 5%(\$)    | 10%(\$)    |
| Francis E. O Donnell, Jr. | 25,000  | 4%  | \$ 2.94                        | August 22, 2015  | \$ 46,500 | \$ 116,750 |
| Mark A. Sirgo             | 28,929  | 5%  | \$ 2.94                        | August 22, 2015  | \$ 53,808 | \$ 135,098 |
|                           | 49,000  | 9%  | \$ 3.03                        | December 1, 2015   | \$ 84,280 | 215,100    |
| Andrew L. Finn            | 8,929   | 2%  | \$ 2.94                        | July 25, 2015  | \$ 16,608 | \$ 41,698  |
|                           | 49,000  | 9%  | \$ 3.03                        | December 1, 2015   | \$ 84,280 | \$ 215,100 |
| Raphael J. Mannino        | 30,714  | 5%  | \$ 2.94                        | August 22, 2015  | \$ 57,128 | \$ 143,434 |
| James A. McNulty          | 26,189  | 5%  | \$ 2.94                        | July 28, 2015  | \$ 48,712 | \$ 122,303 |
|                           | 10,000  | 2%  | \$ 3.03                        | December 1, 2015   | \$ 17,200 | \$ 43,900  |

**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 In-The-Money Options/SARs At Fiscal Year-End(\$) |
|---------------------------------|--------------------------------|--------------------|--|---|
| (a)                             | (b)                            | (c)                | (d)  | (e)   |
| Francis E. O Donnell, Jr., M.D. |                                |                    | 130,000  | \$ 6,650  |
| Mark A. Sirgo, Pharm.D.         |                                |                    | 21,715/61,361  | \$  |
| Andrew L. Finn, Pharm.D.        |                                |                    | 1,715/61,361   | \$  |
| Raphael J. Mannino, Ph.D.       |                                |                    | 274,557/24,315   | \$ 70,400   |
| James A. McNulty                |                                |                    | 13,489/44,551  | \$  |

*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, Jr., Chairman of the Board 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

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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. Dr. O'Donnell relinquished the title of Chief Executive Officer in August 2005 and now serves only as the Chairman of the Board.

(b) Mark A. Sirgo, Pharm.D., President and Chief Executive 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 Executive Officer of the Company at an annual salary of \$250,000. Dr. Sirgo also received a signing bonus in the amount of \$31,177 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 at an annual salary of \$220,000. Dr. Finn also received a signing bonus in the amount of \$28,092 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 us (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 us at an annual salary of \$210,000. Such expired on September 1, 2005, with the effect that, although Dr. Mannino is still an officer and director of the Company in good standing, he currently is employed without an agreement.

(f) Mark W. Salyer, Executive Vice-President of Sales and Marketing On December 2, 2005, Mr. Salyer executed a one-year employment agreement to be the Company's Executive Vice-President of Sales and Marketing beginning January 9, 2006 at an annual salary of \$220,000. The term of this agreement automatically renews for successive one-year terms beginning December 31, 2006 unless terminated on 30-days advance written notice. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

*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.; MARK A. SIRGO, PHARM.D; RAPHAEL J. MANNINO, PH.D.; L.M. STEPHENSON, PH.D.; WILLIAM B. STONE; JOHN J. SHEA AND WILLIAM S. POOLE TO SERVE ON THE COMPANY'S BOARD OF DIRECTORS UNTIL THE 2007 ANNUAL MEETING OR UNTIL THEIR SUCCESSORS ARE DULY ELECTED AND QUALIFIED.**

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**PROPOSAL 2**  
**APPROVAL OF AMENDMENT TO**  
**AMENDED AND RESTATED 2001 INCENTIVE PLAN**  
**TO INCREASE THE NUMBER OF SHARES ISSUABLE THEREUNDER**

*Description of Proposed Amendment*

On June 9, 2006, the Board of Directors unanimously approved an amendment (the **Plan Amendment**) to the Company's Amended and Restated 2001 Stock Incentive Plan (the **Plan**), subject to stockholder approval, to increase the number of shares of Common Stock reserved and available for issuance under the Plan from 2,100,000 to 3,500,000, such amendment to be effected upon approval by the stockholders. The full text of the proposed Plan Amendment is set out in Annex A to this Proxy Statement. The text of the proposed Plan Amendment is subject to modification to include such changes as the Board of Directors deems necessary and advisable to effect the increase in the number of shares of Common Stock reserved and available for issuance under the Plan. Stockholders are being asked to approve the Plan Amendment.

*Vote Required and Recommendation*

The approval of the Plan Amendment to increase the number of shares of Common Stock reserved and available for issuance under the Plan will be made upon the affirmative vote of the majority of shares voting on the proposal. Abstentions and brokers non-votes will have no effect on the outcome. If the proposal is not approved by the stockholders, the Plan Amendment will not be effective and the proposal will not be implemented.

*Reasons for the Plan Amendment*

The purpose of the Plan is to enable the Company to obtain and retain competent personnel who will contribute to the Company's success by their ability, ingenuity and industry, and to provide incentives to such personnel and members that are linked directly to increases in stockholder value, and will therefore, inure to the benefit of all stockholders of the Company. Eligible recipients of awards under the Plan include employees, directors, consultants and advisors of the Company. Currently, awards consisting of deferred stock, restricted stock and options to purchase shares of Common Stock and issued under the Plan total 2,185,595 shares of Common Stock and there are therefore no shares of Common Stock reserved and available for issuance under the Plan. All proposed issuances of options heretofore made which are in excess 2,100,000 shares (totaling 85,595 shares) were issued to the holders thereof conditioned upon approval by stockholders of the Plan Amendment and, and such issuances will be revoked if this proposal is not approved.

The Board of Directors determined to increase the number of shares of Common Stock reserved and available for issuance under the Plan because it believes that the current number is insufficient for the purposes of the Plan as stated above. The market for quality personnel is competitive, and the ability to obtain and retain competent personnel is of great importance to the Company's business operations.

*Effects of the Plan Amendment*

As a result of the Plan Amendment, there will be an increase in the total number of shares of Common Stock reserved for issuance under the Plan. This will provide the Company with the ability to grant more awards than are currently available under the Plan to eligible recipients including employees,



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directors, consultants and advisors. The issuance in the future of awards under the Plan consisting of deferred stock, restricted stock and options to purchase shares of Common Stock may have the effect of diluting the earnings per share and book value per share, as well as the stock ownership and voting rights, of the holders of the currently outstanding shares of Common Stock. The effective increase in the number of authorized but unissued shares of Common Stock which may be issued as awards under the Plan may be construed as having an anti-takeover effect by permitting the issuance of shares to purchasers who might oppose a hostile takeover bid or oppose any efforts to amend or repeal certain provisions of the the Company s Certificate of Incorporation or Bylaws. Holders of the Common Stock have no preemptive or other subscription rights.

*Securities Authorized for Issuance Under Equity Compensation Plans*

| Plan category  | Number of securities<br>to be issued upon<br>exercise of<br>outstanding options,<br>warrants and rights<br>(a) | Weighted-average<br>exercise price of<br>outstanding options,<br>warrants and rights<br>(b) | Number of securities<br>remaining available<br>for future issuance<br>(c) |
|--|--|---|---|
| Equity compensation plans approved by security holders     | 2,100,000  | \$ 4.49   |   |
| Equity compensation plans not approved by security holders | 85,595   | \$ 3.03   |   |
| <b>Total</b>   | <b>2,185,595</b>   | <b>\$ 4.43</b>  |   |

*Recommendation of the Board of Directors*

**THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE APPROVAL OF THE AMENDMENT TO THE AMENDED AND RESTATED 2001 INCENTIVE PLAN.**

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**PROPOSAL 3**

**APPROVAL OF ISSUANCE OF CERTAIN SHARES OF COMMON STOCK AND WARRANTS**

**ISSUED TO CDC IV, LLC IN ACCORDANCE WITH**

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

*Introduction*

The purpose of Proposal 3 is to obtain the stockholder approval necessary under applicable Nasdaq Stock Market rules to allow for the full issuance and exercise of: (i) shares of Common Stock and (ii) two separate warrants to purchase shares of Common Stock (the **Warrants**) issued by the Company to CDC IV, LLC ( **CDC** ).

*Background*

On May 16, 2006, the Company consummated a transaction with CDC pursuant to which \$7 million in funds previously committed by CDC in July 2005 to fund the clinical development of the Company's BEMA<sup>™</sup> Fentanyl product were converted into shares of Common Stock at \$3.50 per share. As a result of this transaction, CDC was issued 2 million shares of Common Stock in return for accelerating the funding of the \$4.2 million balance of \$7 million of aggregate commitment under the Company's July 2005 agreements with CDC and for eliminating the \$7 million milestone payable to CDC upon the approval by the Food and Drug Administration ( **FDA** ) of BEMA<sup>™</sup> Fentanyl. The 2 million shares of Common Stock granted to CDC in the transaction were equivalent to a price of \$3.50 per share based on the total \$7 million funded. In addition, on May 16, 2006, CDC was issued a Warrant (the **May 2006 Warrant**) to purchase up to an additional 904,000 shares of Common Stock at \$3.00 per share. Until such time as the shares of Common Stock underlying the May 2006 Warrant are registered with the Securities and Exchange Commission, CDC shall have the right to exercise the May 2006 Warrant on a cashless basis. In addition, until the date that is ninety (90) days subsequent to regulatory approval of BEMA<sup>™</sup> Fentanyl, the exercise price of the May 2006 Warrant will be reduced to a price equal to the per share price of issuances of securities by the Company at less than the exercise price of the May 2006 Warrant.

On July 15, 2005, the Company entered into a clinical development and license agreement with CDC pursuant to which CDC was to provide up to \$7 million in funding for the clinical development of BEMA<sup>™</sup> Fentanyl. Following an up front payment of \$2 million made in February 2006, the Company was receiving equal monthly payments in accordance with the expected timeline for the BEMA<sup>™</sup> Fentanyl Phase III development program. Under July 2005 agreement, the Company was to repay the \$7 million to CDC within 60 days of approval by FDA of BEMA<sup>™</sup> Fentanyl. Under the amended CDC transaction entered into on May 16, 2006, the full \$7 million commitment was immediately converted into shares of Common Stock and the Company received an immediate cash infusion of \$4.2 million, the balance of the CDC committed funds. As under the original arrangement, CDC will receive royalties based on net sales of BEMA<sup>™</sup> Fentanyl. Pursuant to the CDC development agreement, and concurrently with the timing of CDC's initial \$2.0 million payment to the Company in February 2006, the Company entered into a security agreement granting CDC a security interest in assets related to BEMA<sup>™</sup> Fentanyl. Such security agreement remains in place, and, as in the original agreement, the security interest granted to CDC will terminate on FDA approval of BEMA<sup>™</sup> Fentanyl. However, the clinical development and license agreement and security agreement were amended in the present transaction to eliminate the obligation of the Company to reimburse CDC \$7 million prior to the release of CDC's security interest in BEMA<sup>™</sup> Fentanyl.

Additionally, in connection with the July 2005 transaction with CDC, the Company issued CDC a Warrant (the **July 2005 Warrant**) to purchase up to 500,000 shares of Common Stock at an exercise price

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of \$3.50 per share. As a result of the anti-dilution provisions of the July 2005 Warrant and the pricing of the Company's October 2005 public offering, the conversion price of the July 2005 Warrant is now \$2.91 and the number of shares of Common Stock receivable thereunder increased to 601,120 shares.

In accordance with Nasdaq Stock Market rules, the aggregate number of shares of Common Stock issued or issuable by the Company: (i) upon exercise of all or any portion of the May 2006 Warrant and (ii) upon exercise of the July 2005 Warrant, when added together with the 2 million shares of Common Stock issued to Purchaser pursuant to the May 16, 2006 transaction (collectively, the **Aggregated Shares**), shall not exceed 19.99% of the outstanding shares of Common Stock as of May 16, 2006 (the **Maximum Common Stock Issuance**), unless the issuance of that number of Aggregated Shares that would result in CDC owning in excess of the Maximum Common Stock Issuance (the **CDC Overage Amount**) shall first be approved by the Company's stockholders.

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

The Common Stock is listed on the Nasdaq Capital Market and, as such, the Company is subject to the Nasdaq 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.

On May 16, 2006, there were 11,938,146 shares of Common Stock outstanding. The Nasdaq Stock Market Staff has aggregated the 2 million shares of Common Stock issued to CDC on May 16, 2006 together with the shares of Common Stock underlying the Warrants (a total potential of 3,505,120) as having been issued as part of the same transaction, which amount is in excess of 20% of the outstanding shares of Common Stock on May 16, 2006. Shares of Common Stock issuable upon the exercise of the Warrants are considered common stock issued for purposes of determining whether the 20% limit has been reached. The Nasdaq Staff has further taken the position that, as a result of the weighted average anti-dilution protection afforded to CDC under the Warrants, there is a potential that shares of Common Stock could be issued at less than the market value of the Common Stock on May 16, 2006 and, therefore, the Nasdaq 20% Financing Rule is implicated. Therefore, the Maximum Common Stock Issuance equals 2,387,629 shares of Common Stock and the CDC Overage Amount is equal to 1,117,491 shares of Common Stock. The Company's stockholders are being asked to approve the potential issuance to CDC of the CDC Overage Amount.

### *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 CDC Overage Amount.

### *Recommendation of the Board of Directors*

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

Table of Contents**PROPOSAL 4****RATIFICATION OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY****AS THE COMPANY S INDEPENDENT AUDITORS FOR FISCAL 2006**

On January 27, 2006, 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, 2005 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 2005 and fiscal 2004.

|                    | 2005      | 2004      |
|--------------------|-----------|-----------|
| Audit Fees         | \$ 59,195 | \$ 85,000 |
| Audit-Related Fees | \$ 52,360 | \$ 34,025 |
| Tax Fees           | \$ 16,554 | \$ 17,600 |
| 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, 2005 and 2004, the review of the financial statements included in the Company s Forms 10-QSB totaled, respectively, \$59,195 and \$85,000. The above amounts include interim procedures 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, 2005 and 2004 were \$52,360 and \$34,025, respectively.

**Tax Fees.** The aggregate fees billed by AP for professional services rendered for tax compliance, for the years ended December 31, 2005 and 2004 were \$16,554 and \$17,600, 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, 2005 and 2004 totaled zero 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 2005. 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 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, 2006.**

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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 there were 13,938,146 shares of Common Stock outstanding, 1,647,059 shares of the Company's Series A Convertible Preferred Stock ( **Series A Preferred** ) outstanding and 341,176 shares of the Company's Series B Convertible Preferred Stock ( **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.

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

The following table sets forth, as of June 23, 2006, certain information as to the stock ownership of each person known by the Company to own beneficially five (5%) percent 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 of<br>Common Stock Owned <sup>(1)</sup> | Percentage of Class as of<br>June 23, 2006 |
|--|--|--|
| Hopkins Capital Group II, LLC <sup>(2)</sup>                       | 3,652,756  | 26.2%                                      |
| Francis E. O' Donnell, Jr., M.D. <sup>(3)</sup>                    | 3,986,212  | 28.6%                                      |
| The Francis E. O' Donnell, Jr. Irrevocable Trust #1 <sup>(4)</sup> | 3,820,256  | 27.4%                                      |
| CDC IV, LLC <sup>(5)</sup>   | 2,601,120  | 18.7%                                      |
| Jonnie R. Williams, Sr. <sup>(6)</sup>                             | 3,744,288  | 26.5%                                      |
| MOAB Investments, LP <sup>(7)</sup>                                | 3,698,523  | 26.5%                                      |
| Laurus Master Fund, Ltd. <sup>(8)</sup>                            | 583,499  | 4.99%                                      |
| Mark A. Sirgo, Pharm.D. <sup>(9)</sup>                             | 41,515   | *  |
| Andrew L. Finn, Pharm.D. <sup>(10)</sup>                           | 1,715  | *  |
| Raphael J. Mannino, Ph.D. <sup>(11)</sup>                          | 429,566  | 3.1%                                       |
| Mark W. Salyer <sup>(12)</sup>                                     | -0-  | *  |
| James A. McNulty <sup>(13)</sup>                                   | 92,148   | *  |
| L.M. Stephenson, Ph.D <sup>(14)</sup>                              | 155,500  | 1.1%                                       |
| William B. Stone <sup>(15)</sup>                                   | 185,000  | 1.3%                                       |
| John J. Shea <sup>(16)</sup>                                       | 105,000  | *  |
| William S. Poole <sup>(17)</sup>                                   | 35,000   | *  |
| All Directors and Officers as a group (9 persons)                  | 5,031,656  | 36.1%                                      |

\* Less than 1%

<sup>(1)</sup> Based on 13,938,146 shares of Common Stock outstanding as of June 23, 2006.

<sup>(2)</sup> 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 are presently convertible into shares of Common Stock at March 31, 2006.

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- (3) Dr. O'Donnell is the Company's Chairman of the Board and a Director. 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 130,000 shares of Common Stock, all of which is currently exercisable. Dr. O'Donnell's address is 709 The Hampton Lane, Chesterfield MO 63017.
- (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) Includes 2,000,000 shares of Common Stock issued to CDC IV, LLC on May 16, 2006 and a warrant to purchase 601,120 shares of Common Stock with an exercise price of \$2.91, issued on July 15, 2005. Excludes a warrant to purchase 904,000 shares of Common Stock issued on May 16, 2006 with an exercise price of \$3.00 per share, which is not exercisable until November 16, 2006. CDC IV, LLC's address is 47 Hulfish Street Suite 310, Princeton NJ. 08542. The maximum number of shares of Common Stock issuable to CDC is subject to stockholder approval at the stockholders' meeting to which this Proxy Statement relates. See Proposal 3.
- (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' wife. Mr. Williams' 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) Up to a maximum potential of 3,014,311 shares of Common Stock are issuable upon full conversion or exercise, as the case may be, of the February and May 2005 notes and warrants and the Company's June and December 2005 warrants with Laurus Master Fund, Ltd. ( **Laurus** ). However, the terms of the convertible notes and warrants issued by us to Laurus provide that Laurus is not entitled to receive shares upon exercise of the warrants, upon payment of principal and interest on the notes, or upon conversion of the notes if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of Common Stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to us or without notice upon an event of default). Laurus' address is 825 Third Avenue, 14th Floor, New York, NY 10022.
- (9) Includes 19,800 shares owned by Dr. Sirgo, the Company's President and Chief Executive Officer. 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. Includes options to purchase 20,000 shares of Common Stock, all of which are currently exercisable. Excludes options to purchase 61,361 shares of Common Stock which are not currently exercisable. Dr. Sirgo's address is 3100 Stone Gap Court Raleigh, North Carolina 27612.
- (10) Dr. Finn is the Company's Executive Vice President of Clinical Development and Regulatory Affairs. 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. Excludes options to purchase 61,361 shares of Common Stock which are not currently exercisable. Dr. Finn's address is 737 West Hargett Street, Raleigh, NC 27603.
- (11) Dr. Mannino is the Company's Executive Vice President, Chief Scientific Officer and a Director. Includes 155,009 shares owned and options to purchase 274,557 shares of Common Stock, all of which are currently exercisable. Excludes options to purchase 25,315 shares of Common Stock which are not currently exercisable.

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<sup>(12)</sup> Mr. Salyer is the Company's Executive Vice-President of Sales and Marketing. Excludes 100,000 options to purchase shares of Common Stock, none of which are currently exercisable. His address is 205 Larkwood Lane, Cary, North Carolina 27511.



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- (13) Mr. McNulty is the Company's Chief Financial Officer, Secretary and Treasurer. Includes 76,371 shares owned and options to purchase 13,489 shares of Common Stock, all of which are currently exercisable. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. Excludes options to purchase 44,551 shares of Common Stock which are not currently exercisable. Mr. McNulty's address is 4419 W. Sevilla Street, Tampa, FL 33629.
- (14) Includes options to purchase 120,000 shares of Common Stock, all of which are currently exercisable. Dr. Stephenson's address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.
- (15) Includes options to purchase 150,000 shares of Common Stock, all of which are currently exercisable. Mr. Stone's address is 11120 Geyer Down Lane, Frontenac MO 63131.
- (16) Includes options to purchase 95,000 shares of Common Stock, all of which are currently exercisable. Mr. Shea's address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.
- (17) Includes options to purchase 35,000 shares of Common Stock, all of which are currently exercisable. Mr. Poole's address is 1301 Kings Grant Drive, Raleigh, NC 27614.

**Deadline for Submission of Stockholder Proposals for 2007 Annual Meeting of Stockholders**

Stockholders may present proposals for inclusion in the Proxy Statement for the 2007 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 2007 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 2006 Annual Report to Stockholders, which includes the Company's Annual Report on Form 10-KSB for the year ended December 31, 2005. 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 2005 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 on the SEC's website at [www.sec.gov](http://www.sec.gov).

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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Annex A

**AMENDMENT NO. 1**

**TO**

**BIODELIVERY SCIENCES INTERNATIONAL, INC.**

**AMENDED AND RESTATED 2001 INCENTIVE PLAN**

Pursuant to Section 9 of the Amended and Restated 2001 Stock Plan (the **Plan**) of BioDelivery Sciences International, Inc. (the **Company**) the Board of Directors of the Company has duly adopted a resolution, conditioned upon approval by the stockholders of the Company, approving this Amendment No. 1 to the Plan to increase the total number of shares of common stock, par value \$.001 per share, of the Company (the **Common Stock**) reserved and available for issuance under the Plan as follows:

Section 4.1 of Plan is hereby amended to read in its entirety as follows:

4.1 MAXIMUM NUMBER OF SHARES ISSUABLE. Subject to adjustment as provided in Section 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be Three Million Five Hundred Thousand (3,500,000) and shall consist of authorized but unissued or reacquired shares of Stock, treasury shares, or any combination thereof. If an outstanding Option for any reason expires or is terminated or canceled or if shares of Stock are acquired upon the exercise or Award of an Option or Restricted Share Agreement subject to a Company repurchase option and are repurchased by the Company, the shares of Stock allocable to the unexercised portion of such Option or such repurchased shares of Stock shall again be available for issuance under the Plan.

All other terms and provisions of the Plan shall remain unchanged and in full force and effect as written.

A majority in voting interest of the stockholders present in person or by proxy and entitled to vote at the meeting of stockholders at which this Amendment No. 1 was considered, has duly approved this Amendment No. 1 to the Plan.

**IN WITNESS WHEREOF**, this Amendment No. 1 is made effective this \_\_\_\_ day of \_\_\_\_\_, 2006.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By:

Name:

Title:

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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 MARK A. SIRGO 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 23, 2006, AT THE ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON THURSDAY, JULY 27, 2006, OR ANY ADJOURNMENT THEREOF.

1. To elect seven directors to serve until the 2007 annual meeting of the stockholders.

“ 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.

Mark A. Sirgo

Raphael J. Mannino

William B. Stone

John J. Shea

L.M. Stephenson

William S. Poole

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

2. To approve an amendment to the Company's Amended and Restated 2001 Incentive Plan to increase the number of shares of common stock reserved for issuance under such plan from 2,100,000 to 3,500,000;

“ FOR “ AGAINST “ ABSTAIN

3. To approve and ratify the terms of the issuance by the Company of 2,000,000 shares of Company common stock and a warrant to purchase 904,000 shares common stock issued to CDC IV, LLC on May 16, 2006 (aggregated with a previously warrant to purchase 601,120 shares of common stock issued to CDC IV, LLC on July 15, 2006) in accordance with Nasdaq Marketplace Rule 4350(i)(1)(D)(ii);

“ FOR “ AGAINST “ ABSTAIN

4. 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, 2006; and

“ FOR            “ AGAINST            “ ABSTAIN

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

**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 \_\_\_\_\_, 2006**

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.