BIODELIVERY SCIENCES INTERNATIONAL INC
Form PRE 14A
June 16, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the

Securities Exchange Act of 1934

Filed by the Registrant x Filed by a Party other than the Registrant ¨

Check the appropriate box:

x 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)

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

Payment of Filing Fee (Check the appropriate box):

x No fee required.

¨ Fee computed on table below per Exchange Act Rules 14a-6(i)(4) and 0-11.

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

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

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(5) Total fee paid:

¨ Fee paid previously with preliminary materials.

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

(1) Amount Previously Paid:

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(2) Form, Schedule or Registration Statement No.:

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(3) Filing Party:

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(4) Date Filed:

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

UMDNJ New Jersey Medical School

Administrative Building 4

185 South Orange Avenue

Newark, New Jersey 07103

June 29, 2004

To the Stockholders of BioDelivery Sciences International, Inc.:

BioDelivery Sciences International, Inc. (the Company) is pleased to send you the enclosed notice of the 2004 Annual Meeting of Stockholders of the Company (the Meeting) to be held at 10:00 a.m. on Thursday, July 29, 2004 at the offices of the Public Health Research Institute, 225 Warren Street, Newark, NJ 07103.

The items of business for the Meeting are listed in the following Notice of Annual Meeting and are more fully addressed in the attached Proxy Statement. The Proxy Statement is first being mailed to stockholders of the Company on or about June 29, 2004.

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

If you have any questions regarding this material, please do not hesitate to call me at (314) 579-9725.

Sincerely yours,

/s/ Francis E. O Donnell, Jr.

Francis E. O Donnell, Jr.

Chairman, President and Chief Executive Officer

BioDelivery Sciences International, Inc.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

UMDNJ New Jersey Medical School

Administrative Building 4

185 South Orange Avenue

Newark, New Jersey 07103

NOTICE OF 2004 ANNUAL MEETING OF STOCKHOLDERS

To be held on Thursday July 29, 2004

Notice is hereby given that the Annual Meeting of Stockholders (the Meeting) of BioDelivery Sciences International, Inc., a Delaware Corporation (the Company) will be held on Thursday, July 29, 2004 at 10:00 a.m. at the offices of the Public Health Research Institute, 225 Warren Street, Newark, NJ 07103 for the purpose of considering and voting upon the following matters:

1. To elect all eight (8) members of the Company s Board of Directors to serve until the 2005 Annual Meeting of Stockholders or until their successors are duly elected and qualified;

2. To ratify the appointment by the Audit Committee of the Board of Directors of the Company of Aidman, Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2004; and

3. To transact such other business as may properly come before the meeting or any adjournment thereof.

The foregoing items of business are more fully described in the Proxy Statement accompanying this Notice of Meeting. The Board of Directors has no knowledge of any other business to be transacted at the Meeting or any adjournment or postponement thereof.

The Board of Directors has fixed the close of business on June 24, 2004 as the record date for the determination of stockholders entitled to notice and to vote at the Meeting or any adjournment or postponement thereof. A list of such stockholders will be available for examination by any stockholder, for any purpose germane to the Meeting, during ordinary business hours for ten days prior to the Meeting at the office of the Secretary of the Company at the above address, and at the time and place of the Meeting.

If you would like to attend the Meeting and your shares are held by a broker, bank or other nominee, you must bring to the Meeting a recent brokerage statement of a letter from the nominee confirming you beneficial ownership of such shares. You must also bring some form of personal identification. In order to vote your shares at the meeting, you must obtain from the nominee a proxy issued in you name.

A copy of the Company s Annual Report to Stockholders for the year ended December 31, 2003, which contains financial statements and other information of interest to stockholders accompanies this Notice of Meeting and the enclosed Proxy Statement.

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Stockholders are cordially invited to attend the Meeting in person. **However, to ensure 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.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ James A. McNulty

James A. McNulty

Secretary, Treasurer and Chief Financial Officer

Newark, New Jersey

June 29, 2004

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

UMDNJ New Jersey Medical School

Administrative Building 4

185 South Orange Avenue

Newark, New Jersey 07103

(973) 972-0015

PROXY STATEMENT

ANNUAL MEETING OF STOCKHOLDERS

to be held on Thursday July 29, 2004

at the offices of the Public Health Research Institute

225 Warren Street, Newark, NJ 07103.

INTRODUCTION

2004 Annual Meeting of Stockholders

This Proxy Statement is being furnished to holders of shares of Common Stock, $.001 par value (the Common Stock) of BioDelivery Sciences International, Inc., a Delaware corporation (BioDelivery or the Company), in connection with the solicitation of proxies by the board of directors of the Company (the Board of Directors) for use at the 2004 Annual Meeting of Stockholders (the Meeting) to be held at the offices of offices of the Public Health Research Institute, 225 Warren Street, Newark, NJ 07103 on Thursday July 29, 2004 at 10:00 a.m., and at any adjournment(s) or postponements thereof.

Record Date; Mailing Date

The Board of Directors has fixed the close of business on June 24, 2004 as the record date for the determination of stockholders entitled to notice of, and to vote and act at, the Meeting. Only stockholders of record at the close of business on that date are entitled to notice of, and to vote and act at, the Meeting. The Proxy Statement is first being mailed to stockholders of the Company on or about June 29, 2004.

A COPY OF THE COMPANY S ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2003 AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION (THE SEC), EXCLUDING EXHIBITS, WILL BE FURNISHED WITHOUT CHARGE TO ANY STOCKHOLDER UPON WRITTEN REQUEST TO THE COMPANY, BIODELIVERY SCIENCES INTERNATIONAL, INC., UMDNJ NEW JERSEY MEDICAL SCHOOL, ADMINISTRATIVE BUILDING 4, 185 SOUTH ORANGE AVENUE, NEWARK, NEW JERSEY 07103, ATTENTION JAMES A. MCNULTY. EXHIBITS WILL BE PROVIDED UPON WRITTEN REQUEST AND PAYMENT OF AN APPROPRIATE PROCESSING FEE.

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Proposals to be Submitted at the Meeting

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

1. To elect all eight (8) members of the Company s Board of Directors to serve until the 2005 Annual Meeting of Stockholders or until their successors are duly elected and qualified;

2. To ratify the appointment by the Audit Committee of the Board of Directors of the Company of Aidman, Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2004; and

3. To transact such other business as may properly come before the meeting or any adjournment thereof.

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Beneficial Ownership of our Principal Stockholders, Officers and Directors

The following table sets forth, as of May 1, 2004, certain information as to the stock ownership of each person known by us to own beneficially 5% or more of our outstanding common stock, of each of our 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, we have 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. Unless otherwise indicated, the address for each person listed below is in care of the Company at UMDNJ Medical School 185 South Orange Avenue, Bldg. #4, Newark, New Jersey 07103.

Name of Beneficial Owner	Number of Shares of Common Stock Owned (1)	Percentage of Class as of June 24, 2004
Hopkins Capital Group II, LLC [2]	3,111,580	43.9%
Francis E. O Donnell, Jr., M.D.[3]	3,289,613	46.4%
Pharmaceutical Product Development, Inc. [4]	690,000	9.7%
Jonnie R. Williams, Sr. [5]	3,203,114	45.8%
Dennis Ryll, M.D. [6]	3,157,347	45.2%
Raphael J. Mannino, Ph.D. [7]	397,991	6.0%
James A. McNulty [8]	76,659	1.1%
Donald L. Ferguson [9]	274,600	3.9%
Susan Gould-Fogerite, Ph.D. [10]	186,498	2.6%
L.M. Stephenson, Ph.D [11]	85,000	1.2%
William B. Stone [12]	105,000	1.5%
James R. Butler [13]	50,000	*
John J. Shea [14]	45,000	*
Robert G.L. Shorr [15]	45,000	*
Alan Pearce [16]	50,000	*
All Directors and Officers as a group (12 persons)	4,632,961	66.3%

* Less than 1%

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(1) Based on 6,985,863shares of common stock outstanding as of June 24, 2004, the record date.

(2) Hopkins Capital Group II, LLC is owned one third by each of: (i) various trusts of the O Donnell family; (ii) John R. Williams, Sr. and his family trusts; and (iii) MOAB L.L.C., which is beneficially owned by Dennis Ryll and members of his family.

(3) Dr. O Donnell is our President, Chief Executive Officer, Chairman 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 he disclaims beneficial interest of. The remaining 4,576 shares of common stock are owned by Dr. O Donnell s sister. In addition, this number includes options to purchase 105,000 shares of the Company s common stock, all of which are currently exercisable. Dr. O Donnell s address is 709 The Hampton Lane, Chesterfield MO 63017.

(4) PPDI s address is 3151 South Seventeenth Street, Wilmington, NC 28412.

(5) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). Also includes 45,767 shares of common stock that are personally owned by Mr. Williams and an additional 45,767 shares owned by Mr. Williams wife. Mr. William s address is 1 Starwood Lane, Manakin-Sabot, VA 23103.

(6) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 1). The remaining 45,767 shares of common stock are personally owned by Dr. Ryll. Dr. Ryll s address is 2595 Red Springs Drive, Las Vegas, NV 89135.

(7) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes options to purchase 249,982 shares of the Company s common stock, all of which are currently exercisable. Dr. Mannino s address is 36 Meadowview Drive, Annandale, NJ 08801.

(8) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. His address is 4419 W. Sevilla Street, Tampa, FL 33629.

(9) Mr. Ferguson is our Senior Executive Vice President. Includes options to purchase 274,600 shares of the Company s common stock, all of which are currently exercisable. Mr. Ferguson s address is 11477 Olde Cabin Road, Suite 110, St. Louis, MO 63141.

(10) Dr. Gould-Fogerite is our Vice President and Director of Innovation and Discovery. Includes options to purchase 34,324 shares of the Company s common stock, all of which are currently exercisable. Her address is 6 Cynthia Court, Annandale, NJ 08801.

(11) Includes options to purchase 85,000 shares of the Company s common stock. Dr. Stephenson s address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.

(12) Includes options to purchase 105,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Stone s address is 11120 Geyers Down Lane, Frontenac MO 63131.

(13) Includes options to purchase 50,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Butler s address is 109 Cutter Court, Ponte Vedra Beach, FL 32082.

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(14) Includes options to purchase 45,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Shea s address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.

(15) Includes options to purchase 45,000 shares of the Company s common stock, all of which are currently exercisable. . Mr. Shorr s address is 28 Brookfall Road, Edison, NJ 08817.

(16) Includes options to purchase 50,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Pearce s address is 255 Eagle Ct. Alamo, CA 94507.

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Information Concerning Solicitation and Voting

As of the Record Date, there were 6,985,863 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 and 2.

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

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

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

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE FOR THE APPROVAL OF EACH OF THE PROPOSALS (PROPOSALS 1 AND 2) TO BE SUBMITTED AT THE MEETING.

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PROPOSAL 1

ELECTION OF DIRECTORS

Introduction

The Company s Board of Directors consists of one class of directors having eight (8) 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 eight (8) the number of directors to be elected at the 2004 Annual Meeting. At the Meeting, the stockholders will be asked to elect Francis E. O Donnell, Jr., Raphael J. Mannino, William B. Stone, James R. Butler, John J. Shea, L.M. Stephenson, Robert G.L. Shorr and Alan Pearce (the Nominees) to serve in such capacity until the 2005 Annual Meeting, or until their successors are duly elected and qualified.

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

Directors and Executive Officers

Set forth below is the name and age of each nominee for director and the positions and offices held by him with the Company, his principal occupation and business experience during the past five years, the names of other publicly held companies of which he serves as a director and the year of commencement of his term as a director of the Company.

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	54	Chairman, President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	57	Executive Vice President, Chief Scientific Officer and Director
James A. McNulty	53	Secretary, Treasurer and Chief Financial Officer
Donald L. Ferguson	55	Senior Vice President
Susan Gould-Fogerite, Ph.D.	51	Vice President and Director of Innovation and Discovery
L.M. Stephenson, Ph.D.	61	Director
William B. Stone	61	Director
James R. Butler	63	Director
John J. Shea	77	Director
Robert G.L. Shorr	50	Director
Alan Pearce	55	Director

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

None of our 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 54, has been the Chairman of and a member of the Board of Directors of the Company since October 2001. He has also served as President and Chief Executive Officer on a full-time basis since March 29, 2002. At this time, the Company has not identified a replacement for Dr. O Donnell. He is also the President, Chief Executive Officer and a Director of our subsidiary, Bioral Nutrient Delivery, LLC, since its formation on January 8, 2003. 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. Many of these portfolio companies have business relationships with the Company. 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 served as Chairman of Laser Sight Inc. (LASE), a publicly-traded manufacturer of advanced refractive laser systems, from 1993 through June 12, 2003. He currently serves as co-Chairman of Biovest International, Inc. 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. Dr. O Donnell s address is 709 The Hamptons Lane, Chesterfield, MO 63017.

Raphael J. Mannino, Ph.D., age 57, has been the Executive Vice President and Chief Scientific Officer of the Company since October 2000, and a member of the Board of Directors of the Company since October 2001. Dr. Mannino served as President, CEO, Chief Scientific Officer and member of the board of directors of BioDelivery Sciences, Inc., our predecessor entity, from its incorporation in 1995 until its merger with and into the Company in January of 2002. 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.

James A. McNulty, age 53, has served as the 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 also, since its formation on January 8, 2003, served as the Secretary, Treasurer and Chief Financial Officer of our subsidiary, Bioral Nutrient Delivery, LLC and since May 2000, has 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., and many of the Hopkins Capital Group portfolio companies have relationships with the Company. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida s largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002, he served as CFO/COO of American Prescription Providers, Inc. He is a principal in Pinnacle Group Holdings, a real estate development company developing a major downtown Tampa destination entertainment complex. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty received his B.A. in accounting in 1972 from the University of South Florida. He was licensed as a Certified Public Accountant in 1975 and is a member of the American and Florida Institutes of CPAs. Mr. McNulty s address is 4419 W. Sevilla Street, Tampa, FL 33629.

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Donald L. Ferguson, age 55, has been the Company s Senior Vice President on a part-time basis since October 2000. Mr. Ferguson has been Chief Executive Officer and principal owner of Land Dynamics, Inc., a developer of real estate projects since its founding in 1979 and currently owns in excess of 20 real estate properties. Mr. Ferguson is an investor in early-stage technology and biotechnology companies, including Nanovision Technologies, Inc., Star Scientific, Inc., BioKeys Pharmaceuticals, Inc. and PhotoVision Pharmaceuticals, Inc. Mr. Ferguson holds an M.B.A. Degree from the University of Kansas and a B.S. Degree in industrial engineering from Oklahoma State University.

Susan Gould-Fogerite, Ph.D., age 51, has been the Company s Vice President and Director of Innovation and Discovery since July 2002 and has been a member of the board of directors of our subsidiary, Bioral Nutrient Delivery, LLC, since its formation on January 8, 2003. She was previously Executive Vice President of Business Development Vaccines and Gene Therapy from October 2000. Dr. Gould-Fogerite served as Vice President and Secretary and has been a member of the board of directors of BioDelivery Sciences, Inc., our predecessor entity, from its incorporation in 1995 until its merger with and into the Company in January of 2002. Dr. Gould-Fogerite s previous experience includes her positions as Assistant Professor, at University Of Medicine And Dentistry Of New Jersey, New Jersey Medical School (1991 to present), and Research Instructor (1985 to 1988), then Research Assistant Professor (1988-1990), at Albany Medical College. Dr. Gould-Fogerite received her Ph.D. in Microbiology and Immunology from the Albany Medical College in 1985.

L.M. Stephenson, Ph.D., age 61, has been a member of the Board of Directors of the Company since October 2001 and has been a member of the board of directors of our subsidiary Bioral Nutrient Delivery, LLC since its formation on January 8, 2003. Dr. Stephenson is currently Vice Provost for Research at Drexel University. Prior to joining Drexel University in 2003 he was associated with the University of Medicine and Dentistry of New Jersey (UMDNJ) 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. 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 also serves on the board of directors of the following institutions: Kessler Medical Rehabilitation & Research Corporation (Non-Profit), University Heights Sciences Park (Non-Profit), New Jersey Entrepreneurs Network, Rutgers Help Desk & Business Incubator, Crescent Genomics and the New Jersey Research and Development Council. Dr. Stephenson earned his Ph.D. in chemistry from the California Institute of Technology where he earned the Kodak Prize for outstanding chemistry graduate student and was an NSF Predoctoral Fellow. Additionally, Dr. Stephenson was a Research Fellow at Harvard University.

William B. Stone, age 61, has been a member of the Board of Directors of the Company since October 2001 and serves as chairman of the Audit Committee of the Board of Directors. For thirty years, until his retirement in October 2000, Mr. Stone was continuously employed by Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and CIO 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.

James R. Butler, age 63, has been a member of our Board of Directors since March 2002. He is currently a director of Durect Corporation and has served in this capacity since July 1999. Mr. Butler is retired from ALZA Corporation where the last position he held was President of Alza International and from which he retired in June 2001. Mr. Butler was employed at Alza from August 1993 to June 2001. Prior to that, Mr.

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Butler worked at Glaxo Inc. for 23 years where the last position he held was Vice President General Manager of Corporate Division. He is currently on the board of directors of Hematrope Pharmaceuticals and is the Chairman of the board of directors of Respirics, Inc. Mr. Butler is on the Pharmacy School Board at the University of Florida and is on the Board of Advisors at Campbell University, North Carolina. Mr. Butler is also an advisor to the Chairman of Reliant Pharmaceuticals, a private pharmaceuticals company. Mr. Butler earned a B.S. in marketing at the University of Florida.

John J. Shea, age 77, has been a member of the Board of Directors of the Company since March 2002. He is currently the head of his own firm of John J. Shea & Associates and a Quality Systems Associate with Quintiles Consulting, a division of The Lewin Group, Inc. . 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, which is responsible for the implementation of quality assurance procedures in a number of public and private 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.

Robert G.L. Shorr, Ph.D., age 50, has been a member of the Board of Directors of the Company since March 2002. He is currently President and CEO of Cornerstone Pharmaceuticals, a company focused on novel tumor targeting drug delivery and novel anticancer agent technologies. He is also on the faculty of State University of New York (SUNY) Stony Brook Department of Biomedical Engineering where he serves as the Director of Business Development for the Center for Advanced Technology State University of New York at Stony Brook. He has served in that position since October 1998. As Director of Business Development for the State University of New York at Stony Brook Center for Biotechnology, Dr. Shorr has been responsible for working with faculty and the university technology transfer office to establish grant funded entrepreneurial programs for promising commercializable technology. From 1991 to 1998, Dr. Shorr served as Vice President Science and Technology and as Vice President for Research and Development at Enzon Inc., a public company. Among his many accomplishments, Dr. Shorr was responsible for management of the co-development with Schering Plough of the product PEG INTRON A, which is now approved in the US and Europe. Dr. Shorr also served as chief scientist for another public company, United Therapeutics, Inc. since 1998 and continues to be a consultant. Dr. Shorr was also Associate Director for Molecular Pharmacology at SmithKline and French Upper Marion, PA; working under the direction of Stanley T. Crooke, M.D., Ph.D. and President of World Wide Research and Development. Dr. Shorr received his B.S. in Biology from the State University of New York (Buffalo) in 1975, his D.I.C. from Imperial College of Science & Technology in London, England in 1982, and his Ph.D., in Biochemistry from the University of London in 1981.

Alan Pearce, age 55, has been a member of the Board of Directors of the Company since September 2002. He recently retired from McKesson Corporation where he had served as Senior Vice President, Financial Services from April 1999 through April 2004. McKesson Corporation, a Fortune 12 company, is the leading provider of supply, information and care management products and services designed to reduce costs and improve quality across healthcare. Prior to this date he was treasurer of McKesson Corporation. Mr. Pearce is a graduate of Georgia Institute of Technology, where he earned a BS in Industrial Management and the University of Texas, where he earned his MBA in finance.

Certain Relationships and Related Transactions

The above-named directors and executive officers have indicated that neither they nor any of their respective affiliates has any relationship with the Company that is required to be disclosed pursuant to Item 404

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of Regulation S-B promulgated under the Securities Exchange Act of 1934, as amended, except for the transactions set forth below.

We have also entered into a letter agreement with BioKeys Pharmaceutical, Inc, a biotechnology company, which is developing several potential products which are vaccine based. To the extent that BioKeys Pharmaceutical, Inc. utilizes our Bioral™ drug delivery technology, we will earn a flat royalty which we will negotiate and be approved by the independent audit committee of the Board of Directors (the Audit Committee). Regent Court Technologies LLC, which is affiliated with one of our stockholders, and Dr. Francis E. O Donnell, our CEO and a director, and Donald L. Ferguson, our senior executive vice-president, are affiliated as stockholders, and Dr. O Donnell is a member of the board of directors, of BioKeys Pharmaceutical, Inc. We had also received a $35,000 loan from BioKeys Pharmaceutical, Inc. to begin research on their products using our technology. The loan was in the form of a demand note with an interest rate of 1% plus prime. The loan has been repaid.

Mr. James McNulty, our current Secretary, Treasurer and part-time Chief Financial Officer, is also the secretary, treasurer and part-time Chief Financial Officer of Bioral Nutrient Delivery, LLC, our wholly owned subsidiary and Biovest International, Inc., a company affiliated with The Hopkins Capital Group. He also serves as the Chief Financial Officer of The Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O Donnell, our president and CEO.

In July 2002 we issued Ellenoff Grossman & Schole LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at $7.00 per share. In March 2004 we issued Ellenoff Grossman & Schole LLP 24,510 shares of our common stock. Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. In connection with the formation of Bioral Nutrient Delivery, LLC, Ellenoff Grossman & Schole LLP received 37,500 Class B Membership Shares of Bioral Nutrient Delivery, LLC.

Certain members of the board and the entities that they are employed by, other than members of the Audit Committee, sometimes have other business relationships with affiliates of the Hopkins Group.

During 2002, we also issued an additional 75,000 options to purchase our common stock to each of the University of Medicine and Dentistry of New Jersey and Albany Medical College in connection with the amendment of our license agreement with such institutions. As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to promoters as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parities. At the time of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present Board of Directors includes four independent directors. These independent directors are William Stone, James Butler, John Shea, Robert Shorr and Alan Pearce.

All future transactions between us and our officers, directors or five percent stockholders, and

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respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel. We intend to maintain at least two independent members on our Board of Directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the reporting persons) file with the Securities and Exchange Commission various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) reports they file. Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in 2003, all Forms 3, 4 and 5 were timely filed with the Securities and Exchange Commission by such reporting persons. We believe there are some delinquent filings in 2004.

Corporate Governance

The Company s Board of Directors has long believed that good corporate governance is important to ensure that the Company is managed for the long-term benefit of stockholders. During the past year, the Companies Board of Directors has continued to review its governance practices in light of the Sarbanes-Oxley Act of 2002 and new SEC rules and regulations. This section describes key corporate governance guidelines and practices that the Company has adopted. Complete copies of the Audit and Nominating and Corporate Governance Committee charters and code of business conduct and ethics described below are available on the Company s website. Alternatively, you can request a copy of any of these documents by writing to the Company.

Meetings of the Board of Directors

The Company s Board of Directors met in person and telephonically five times during 2003 and also acted by unanimous written consent. It is the Company s policy that all directors must attend all meetings, barring extenuating circumstances. All directors participated in the meetings and all directors with the exception of John Shea were present at 75% or more of the Board of Directors meetings held during such director s tenure as a member of the Board of Directors. Mr. Shea attended three of the five meetings held last year.

Committees of the Board of Directors

The Board of Directors has established three standard 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. Current copies of Audit and Nominating and Corporate Governance Committees charters are posted on the Company s website.

The Board of Directors has an Audit Committee, comprised of William B. Stone, James R. Butler and Alan Pearce, 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.

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The Audit Committee met four times last year. Each member of the Audit Committee was present at all of the Audit Committee meetings held during such director s tenure as a member of the Audit Committee. The Audit Committee oversees the Company s corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of, and assesses the qualifications of, the Company s independent auditors, and recommends to the Board of Directors whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors. The Audit Committee reviews and approves the engagement of the independent auditors, prior to commencement of such engagement, to perform any proposed permissible services. The Audit Committee monitors the rotation of partners of the independent auditors on the Company 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 discusses with management and the independent auditors the results of the annual audit and the Company s quarterly financial statements. In addition, the Audit Committee oversees all aspects of the Company s corporate governance functions on behalf of the board. The Audit Committee provides oversight assistance in connection with legal and ethical compliance programs established by management and the board, including Sarbanes-Oxley implementation, and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

The Board of Directors has a Nominating and Corporate Governance Committee, comprised of Alan Pearce, L.M. Stephenson and John J. Shea. Mr. Pearce serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing the Company s corporate governance policies and with proposing potential director nominees to the Board of Directors for consideration. The Nominating and Corporate Governance Committee was formed in May of 2004 and accordingly did not meet during 2003. The Nominating and Corporate Governance Committee has a charter. A current copy of the charter is available to stockholders on the Company s website at http://www.biodeliverysciences.com. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the National Association of Securities Dealers (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 of the Company have previously served in such capacity. During 2003 the Company did not pay any fees to any third parties to assist in the identification of nominees. During 2003, the Company did not receive any director nominee suggestions from stockholders.

The Board of Directors also has a compensation committee, which, either alone or in conjunction with the full board, as the case may be, reviews and recommends the compensation arrangements for our management. The members of the compensation committee are Dr. Francis E O Donnell, Jr., L.M. Stephenson and William B. Stone. The compensation committee did not meet during 2003.

The Board of Directors also has an investment committee, which either alone or in conjunction with the full board, as the case may be, reviews and recommends the investment arrangements for the Company. The members of the investment committee are Frank O Donnell, William Stone, Bill Stephenson, James Butler and Alan Pearce. The investment committee met once during 2003.

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

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Code of Business Conduct and Ethics

The Company has adopted a written code of business conduct and ethics that applies to the Company s directors, officers and employees, including its principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Company has posted a current copy of the code on its website. In addition, the company intends to post on its website all disclosures that are required by law concerning any amendments to, or waiver from, any provision of the code.

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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, James R. Butler and Alan Pearce, each of whom is independent as defined by the rules of the National Association of Securities Dealers. Mr. Stone serves as chairman of the committee. The Board of Directors has adopted a written Audit Committee Charter, which was filed as Appendix A to the Company s 2003 Proxy Statement.

Management is responsible for the Company s financial statements, financial reporting process and systems of internal controls. The Company s independent auditors are responsible for performing an independent audit of the Company s financial statements in accordance with auditing standards generally accepted in the United States and for issuing a report thereon. The Committee s responsibility is to oversee all aspects the financial reporting process on behalf of the Board of Directors. The responsibilities of the Committee also include recommending to the Board of Directors an accounting firm to be engaged 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, 2003. 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/ James R. Butler

/s/ Alan Pearce

* 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 Securities and Exchange Commission, 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.

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Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee during the year ended December 31, 2003 were Dr. Francis E O Donnell, Jr., L.M. Stephenson and William B. Stone. No executive officer of the Company served as a director or member of the Compensation Committee of any other entity, one of whose executive officers served as a member of the Compensation Committee or director of the Company.

Compensation of Directors and Executive Officers

Directors receive options to purchase 20,000 shares of common stock, at the then current market price, for every year of service to the Company. The following table provides the information required under Item 402 of Regulation S-B with respect to executive compensation.

SUMMARY COMPENSATION TABLE*

					Long Term Compensation			
		Annual Compensation(1)			Awards		Payouts	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Restricted Stock Award(s)	Securities Underlying Options/ SARs	LTIP Payouts	All Other Compensation(2)
		($)	($)	($)	($)	(#)	($)	($)
Francis E. O Donnell, Jr., M.D.	2003	$145,962				35,000		
	2002	112,500						
Chairman, President and CEO	2001					61,991		
709 The Hampton Lane						8,009		
Chesterfield, MO 63017								
James A. McNulty,	2003	$141,769				18,616		
	2002							
CFO, Secretary and Treasurer	2001	170,922	$35,000					
4419 W. Sevilla Street		40,000						
Tampa, Florida 33629								
Donald L. Ferguson,	2003							

Senior Executive Vice President Land Dynamics, Inc. 11719 Old Ballas Road, Suite 110 St. Louis, MO 63141	2002 2001			274,600	
Raphael J. Mannino, Ph.D.(3), Executive Vice President, Chief Scientific Officer UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103	2003 2002 2001	$ 90,000 91,500 83,650	52,500	111,449 35,423 96,110	$ 726,957
Susan Gould-Fogerite, Ph.D.(4), Vice President and Director of Innovation and Discovery UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103	2003 2002 2001	$ 63,494 46,660 40,800		19,438 34,324	$ 581,564

* Salary reflects total compensation paid to these executives (pre-merger and post-merger with BioDelivery Sciences, Inc. during these periods).

(1) 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.

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(2) Reflects the increase in value of the permanent discount stock (a variable award) and the compensation expense recorded by us as a result of the agreement to remove the permanent discount and put rights.
(3) Excludes $117,606, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2003 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.
(4) Excludes $94,141, which funds were reimbursed by us during 2003 to the University of Medicine and Dentistry of New Jersey during 2003 (pursuant to a contractual arrangement) for services rendered by Dr. Gould-Fogerite to such university.

Option Grants During Year Ended December 31, 2003

	Individual Grants			Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term		
(a)	(b)	(c)	(d)	(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. M.D.	35,000	11.03%	$ 3.83	August 14, 2013	$ 6,702.50	$ 13,405.00
Raphael J. Mannino, Ph.D.	51,449	16.23%	$ 3.83	August 14, 2013	$ 9,852.48	$ 19,704.97
	60,000	18.92%	$ 1.63	January 31, 2008	$ 25,050.00	$ 30,900.00
James A. McNulty	18,616	5.87%	$ 3.83	August 14, 2013	$ 3,564.96	$ 7,129.93
Donald L. Ferguson						
Susan Gould-Fogerite, Ph.D.	19,438	6.13%	$ 3.83	August 14, 2013	$ 3,722.38	$ 7,444.75

Aggregated Option Exercises in Last Fiscal year and Fiscal Year-End Option Values

No options were exercised during the fiscal year-end December 31, 2003.

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AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name and Principal Position	Shares Acquired On Exercise(#)	Value Realized($)	Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) Exercisable	Unexercisable	Value of Unexercised In-The-Money Options/SARs At Fiscal Year-End($) Exercisable	Unexercisable
(a)	(b)	(c)	(d)		(e)	
Francis E. O Donnell, Jr., M.D. Chairman, President and CEO 709 The Hampton Lane Chesterfield, MO 63017			105,000/0		$ 35,350/0	
Raphael J. Mannino, Ph.D. Executive Vice President, Chief Scientific Officer UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103			242,892/0		$ 85,000/0	
James A. McNulty, CFO Secretary and Treasurer 4419 W. Sevilla Street Tampa, Florida 33629			18,616/18,616			
Donald L. Ferguson			274,600			

Senior Executive Vice President

Land Dynamics, Inc.

11719 Old Ballas Road, Suite 110

St. Louis, MO 63141

Susan Gould-Fogerite, Ph.D. Vice President and Director of Innovation and Discovery UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103	34,324/19,438

Employment Agreements

Except for Dr. Francis E. O Donnell, Mr. James McNulty, Dr. Susan Gould-Fogerite, Dr. Raphael Mannino, Dr. Stephane Allard and James Wachholz we currently have no written employment agreements with any of our officers, directors, or key employees. We may elect to pursue obtaining employment agreements with certain of these individuals at some point in the future. All directors and officers have executed confidentiality and non-compete agreements with us.

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Under our employment arrangements, our officers received the following annualized salaries and other benefits in 2003:

(i) Dr. O Donnell, President, CEO and Chairman On March 29, 2002, Dr. O Donnell executed an employment agreement to be our full-time President and CEO at an annual salary of $150,000. Dr. O Donnell s term of employment shall be no longer than three years or until another CEO candidate is appointed.

(ii) James A. McNulty, CFO, Secretary and Treasurer Although he is a part-time CFO, he has an employment agreement with us (which was amended on August 31, 2002, and again on June 17, 2003) for a base salary of $185,000, which terminates on June 17, 2006. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(iii) Donald Ferguson, Senior Executive Vice President Receives no salary and no benefits.

(iv) 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 agreement terminates on September 1, 2005. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(v) Dr. Susan Gould-Fogerite, Vice President and Director of Innovation and Discovery On August 31, 2002, Dr. Gould-Fogerite executed an employment agreement with us at an annual salary of $146,030. Such agreement terminates on August 31, 2005. Under the terms of this agreement, she is also entitled to the following benefits: medical, dental and disability and 401(k).

Drs. Raphael Maninno and Susan Gould-Fogerite had outstanding debt payable to us, which was incurred with their purchase of stock of BioDelivery Sciences, Inc. in 1999. Simultaneously with the closing of our public offering in June, 2002, we forgave those notes and provided these same individuals with a total of approximately $200,000 as compensation for their tax liability.

Recommendation of the Board of Directors

THE BOARD OF DIRECTORS RECOMMENDS A VOTE FOR THE ELECTION OF EACH OF: FRANCIS E. O DONNELL, JR., M.D.; RAPHAEL J. MANNINO, PH.D.; L.M. STEPHENSON, PH.D.; WILLIAM B. STONE; JAMES R. BUTLER; JOHN J. SHEA; ROBERT G.L. SHORR AND ALAN PEARCE TO SERVE ON THE COMPANY S BOARD OF DIRECTORS UNTIL THE 2005 ANNUAL MEETING OR UNTIL THEIR SUCCESSORS ARE DULY ELECTED AND QUALIFIED.

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PROPOSAL 2

RATIFICATION OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY

AS THE COMPANY S INDEPENDENT AUDITORS FOR FISCAL 2004

On February 6, 2004, with the approval of the Audit Committee and the full Board of Directors of the Company, the firm of Aidman, Piser & Company, P.A. (AP) was appointed as the Company s independent auditors for the fiscal year ending December 31, 2004.

The independent accountant s report of AP on the Company s consolidated financial statements for the year ended December 31, 2003 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 2003.

	2003
Audit Fees	$ 37,426
Audit-Related Fees	$ 26,700
Tax Fees	$ 10,000
All Other Fees	$ 0

Audit Fees

Audit Fees consisted of fees for services rendered to the Company for the audit of the Company s annual financial statements, reviews of the Company s quarterly financial statements and services in connection with statutory or regulatory filings.

Audit Related Fees

Audit-Related Fees consisted of fees incurred for preparation of a registration statement on behalf of our Bioral Nutrient Delivery, LLC subsidiary, and amendments thereto filed with the SEC.

Tax Fees

Tax Fees consisted of services in connection with the preparation of federal and state tax returns and tax compliance.

The Audit Committee has adopted the following pre-approval policies and procedures pursuant to 17 CFR 210.2-01(c)(7)(i):

Management requests a budget from the audit firm for the review and audit services to be rendered. After approval by management of the proposed fees schedule, the Audit Committee approves the budgeted fees. From time to time, budgeted fees have been exceeded, but we receive subsequent approval.

100% of the auditing services, described above, rendered by AP to the Company during fiscal 2003 were approved by the Audit Committee pursuant to 17 CFR 210.2-01(c)(7)(i)(C).

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A representative of Aidman, Piser & Company, P.A. is expected to attend the Annual Meeting. The representative will be offered the opportunity to make any statements he or she may desire and to respond to appropriate stockholder questions.

Our Prior Auditors, Grant Thornton LLP.

On April 18, 2003, the Company, with the approval of the Audit Committee of the Board of Directors and the full Board of Directors, dismissed Grant Thornton LLP (GT) as the Company s independent auditors. During the years ended December 31, 2002 and during the subsequent interim period through April 18, 2003 (the date of GT s dismissal as the Company s independent auditors), GT acted as the independent auditors for the Company and its subsidiary, Bioral Nutrient Delivery, LLC, and, during such period there were no disagreements with GT on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of GT, would have caused GT to make a reference to the subject matter of the disagreements in connection with its reports in the financial statements for such years.

The independent accountant s report of GT on the Company s consolidated financial statements for the year ended December 31, 2002 contained no adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles.

GT has advised the Audit Committee and management that it noted a lack of segregation of accounting and financial reporting duties as a result of the Company s small size, which condition GT considered to be reportable under standards established by the American Institute of Certified Public Accountants. The Company believes this matter is not reportable under Regulation S-B since, among other factors, the noted issue did not preclude the Company from developing reliable financial statements as contemplated by Item 304(a)(1)(iv)(B)(1) of Regulation S-B. The Company voluntarily made the foregoing disclosure, however, in its Current Report on Form 8-K, dated April 18, 2003 and filed on April 25, 2003, as an accommodation to its former independent auditors. The Company has taken GT s notation under advisement but believes its internal accounting controls are in compliance with applicable accounting standards, rules and regulations. The Company will continue to monitor and assess the costs and benefits of additional staffing in the accounting area in conjunction with its newly appointed independent auditors, Aidman, Piser & Company, P.A. The Company has authorized GT to respond fully to the inquiries of Aidman Piser concerning the lack of segregation of accounting and financial reporting duties as a result of the Company s small size.

The following fees were incurred by the Company for the services of Grant Thornton LLP in fiscal 2002 and in fiscal 2003.

	2002	2003
Audit Fees	$ 89,243.00	$ 64,984
Audit-Related Fees	$ 0	$ 0
Tax Fees	$ 20,111.00	$ 3,767
All Other Fees	$ 114,959.00	$ 26,000

Audit Fees

Audit Fees consisted of fees for services rendered to the Company for the audit of the Company s annual financial statements, reviews of the Company s quarterly financial statements and services in connection with statutory or regulatory filings.

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Audit Related Fees

Audit-Related Fees consisted of fees incurred in connection with the Company s Initial Public Offering in fiscal 2002.

Tax Fees

Tax Fees consisted of services in connection with the preparation of federal and state tax returns and advice regarding proposed business combinations.

All Other Fees

All Other Fees consisted of advice regarding the formation of the Company s subsidiary.

The Audit Committee has adopted the following pre-approval policies and procedures pursuant to 17 CFR 210.2-01(c)(7)(i):

Management requests a budget from the audit firm for the review and audit services to be rendered. After approval by management of the proposed fees schedule, the Audit Committee approves the budgeted fees. From time to time, budgeted fees have been exceeded, but we receive subsequent approval.

100% of the auditing services, described above, rendered by GT to the Company during fiscal 2002 and 2003 were approved by the Audit Committee pursuant to 17 CFR 210.2-01(c)(7)(i)(C).

A representative of Grant Thornton LLP is not expected to attend the Annual 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, 2004.

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OTHER INFORMATION

Proxy Solicitation

All costs of solicitation of proxies will be borne by us. In addition to solicitation by mail, our officers and regular employees may solicit proxies personally or by telephone. We do not intend to utilize a paid solicitation agent.

Proxies; Votes Required

A stockholder may revoke his, her or its proxy at any time prior to its use by giving written notice to our Secretary, 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 Board of Directors. Stockholders are entitled to one vote for each share of Common Stock owned. 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 Company s 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.

Securities Outstanding

As of the close of business on June 24, 2004, the record date for the Meeting, there were outstanding 6,985,863 shares of common stock, par value $.001 per share (the Common Stock) and no shares of preferred stock.

Other Business

The 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.

Deadline for Submission of Stockholder Proposals for 2005 Annual Meeting of Stockholders

Stockholders may present proposals for inclusion in the 2005 Proxy Statement 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 2005 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.

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Additional Information

Accompanying this Proxy Statement is a copy of the Company s Annual Report to Stockholders, which includes the Company s Annual Report on Form 10-KSB for the year ended December 31, 2003. 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 our audited financial statements for the 2003 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 Securities and Exchange Commission (the Commission). Such reports, proxy statements and other information are available for inspection and copying at the public reference facilities maintained by the Commission at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, DC 20549, and on the Commission s website at www.sec.gov. Copies of such materials may be obtained upon payment of the Commission s customary charges by writing to the Public Reference Section of the Commission at Judiciary Plaza, 450 Fifth Street, N.W., Washington, DC 20549.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

The undersigned hereby appoint(s) Francis E. O Donnell, Jr. and Raphael J. Mannino with the power of substitution and resubstitution to vote any and all shares of capital stock of Biodelivery Sciences International, Inc. (the Company) which the undersigned would be entitled to vote as fully as the undersigned could do if personally present at the Annual Meeting of the Company, to be held on July 29th, 2004 at 10:00 A.M. local time, and at any adjournments thereof, hereby revoking any prior proxies to vote said stock, upon the following items more fully described in the notice of any proxy statement for the Annual Meeting (receipt of which is hereby acknowledged):

1. ELECTION OF DIRECTORS

VOTE

¨ **FOR ALL nominees listed below EXCEPT as marked to the contrary below**

¨ **WITHHOLD AUTHORITY to vote for ALL nominees listed below**

(INSTRUCTION: To withhold authority to vote for any individual nominee strike a line through the nominee s name below.)

FRANCIS E. O DONNELL, JR., M.D.; RAPHAEL J. MANNINO, PH.D.; L.M. STEPHENSON, PH.D.; WILLIAM B. STONE; JAMES R. BUTLER; JOHN J. SHEA; ROBERT G.L. SHORR AND ALAN PEARCE

2. RATIFICATION OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY LLP AS INDEPENDENT AUDITORS OF THE COMPANY FOR FISCAL 2004

¨ **FOR the ratification of the appointment of AIDMAN, PISER & COMPANY LLP**

¨ **WITHHOLD AUTHORITY**

¨ **ABSTAIN**

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THIS PROXY WILL BE VOTED AS SPECIFIED ABOVE; UNLESS OTHERWISE INDICATED, THIS PROXY WILL BE VOTED FOR ELECTION OF THE EIGHT (8) NOMINEES NAMED IN ITEM 1 AND THE RATIFICATION OF THE APPOINTMENT OF AIDMAN, PISER & COMPANY LLP AS INDEPENDENT AUDITORS OF THE COMPANY FOR FISCAL 2004 IN ITEM 2.

In their discretion, the Proxies are authorized to vote upon such other business as may properly come before the meeting.

Please mark, sign date and return this Proxy promptly using the accompanying postage pre-paid envelope. THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS OF BIODELIVERY SCIENCES INTERNATIONAL, INC.

Dated: _____

Signature

Signature if jointly owned:

Print name:

Please sign exactly as the name appears on your stock certificate. When shares of capital stock are held by joint tenants, both should sign. When signing as attorney, executor, administrator, trustee, guardian, or corporate officer, please include full title as such. If the shares of capital stock are owned by a corporation, sign in the full corporate name by an authorized officer. If the shares of capital stock are owned by a partnership, sign in the name of the partnership by an authorized officer.

PLEASE MARK, DATE, SIGN AND RETURN THIS PROXY PROMPTLY

IN THE ENCLOSED ENVELOPE