Sage Therapeutics, Inc.
Form 10-Q
August 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-36544

Sage Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	27-4486580
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

215 First Street

Cambridge, Massachusetts 02142

(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code: (617) 299-8380

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of July 31, 2017, there were 37,441,084 shares of the registrant's Common Stock, $0.0001 par value per share, outstanding.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “beli “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to develop and commercialize our product candidates in the central nervous system, or CNS, disorders we discuss in this Quarterly Report, and potentially in other indications;
- our ability, within the expected timeframes, to complete our ongoing clinical trials and non-clinical studies; to announce the results of such studies and trials; to advance our product candidates into additional clinical trials, including pivotal clinical trials; and to successfully complete such clinical trials;
- our expectations as to the sufficiency of the planned clinical development programs for our product candidates, if successful, to support regulatory approval; our plans with respect to filing for regulatory approval of our product candidates, if clinical development is successful; and the anticipated review path and potential to obtain regulatory approval and to commercialize any product, if approved;
- our estimates regarding expenses; use of cash; timing of future cash needs; and capital requirements;
- our potential to achieve future revenues;
- our expectations with respect to the availability of supplies of our product candidates, and the expected performance of our third-party manufacturers;
- our expectations with respect to the performance of our contract research organizations and other third parties whose activities are important to our development and future commercialization efforts;
- our ability to obtain and maintain intellectual property protection for our proprietary assets and other forms of exclusivity relevant to our business;
- the estimated number of patients in indications of interest to us; the potential for our product candidates in those indications, if approved; the size of the potential markets for our product candidates; and our ability to serve those markets;
- the anticipated rate and degree of market acceptance, and expectations regarding the availability and level of reimbursement, of our product candidates in any indication if approved;
- our plans for expanding our activities, including outside the U.S., and the potential for future collaborations and other types of contractual relationships, if appropriate, for accomplishing our strategic objectives;
- the level of costs we may incur in connection with our activities, the possible timing and sources of future financings, and our ability to obtain additional financing when needed to fund future operations;
- the potential for success of competing products that are or become available for the indications that we are pursuing or may in the future pursue;
- the potential risk of loss of key scientific or management personnel; and
- other risks and uncertainties, including those listed under Part II, Item 1A, Risk Factors.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, Risk Factors and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or

revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report contains estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Sage Therapeutics, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements
Sage Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$133,450	$168,517
Marketable securities	152,478	228,962
Prepaid expenses and other current assets	5,192	5,100
Total current assets	291,120	402,579
Property and equipment, net	1,443	1,388
Restricted cash	849	564
Total assets	$293,412	$404,531
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$6,042	$12,817
Accrued expenses	26,239	22,352
Total current liabilities	32,281	35,169
	827	845

Other liabilities	
Total liabilities	33,108

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We have limited manufacturing experience, and once our drug formulations or products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed formulations or products are approved for commercial sale, we will need to establish, most likely through third parties, the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products. We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

Due to the fact that we must build our marketing, sales, managed care, and distribution infrastructure and channels, we may be unsuccessful in our efforts to sell our formulations or products.

We expect that we will be required to enter into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products in development. Except for our non-exclusive distribution agreement with BioTech Specialty Partners, Inc., a development-stage company affiliated with Dr. Francis E. O Donnell, a member of our management and significant beneficial owner of our securities, and the agreement between us and TEAMM Pharmaceuticals, also an affiliate of Dr. O Donnell, relating to Emezine®, we have yet to establish marketing, sales or distribution capabilities for our proposed formulations or products. Even though our proposed formulations or products have not been approved by the regulatory authorities, we devote meaningful time and resources in this regard. At the appropriate time, we intend to enter into agreements with third parties to sell our proposed formulations or products, or we may (in the future, resources permitting) develop our own sales and marketing force. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. In particular, our inability to secure a commercial partner for our lead product, BEMA Fentanyl, would seriously compromise our ability to bring this product to market.

If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, especially our lead product BEMA Fentanyl, we will need to develop our own sales and marketing capabilities. Given the late stage of the clinical development of BEMA Fentanyl, it is highly unlikely that we will have the time or resources to develop such capabilities with respect to such product and will have to rely on securing a commercial partner. Moreover, even if we were to develop our own sales and marketing capability, our experience in developing a fully integrated commercial organization is very limited. If we choose to establish a fully integrated commercial organization, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a fully integrated commercial organization on a cost effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

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We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, managed care, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

If we are unable to convince physicians as to the benefits of our proposed formulations or products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our proposed formulations and products and related drug delivery technologies may require physicians to be informed regarding our proposed pharmaceutical formulations or products and the intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed formulations or products. We may be unable to timely educate physicians regarding our intended pharmaceutical formulations or products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our formulations or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our formulations or products is created, if at all.

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey for all of our research activities relating to our Bioral® technology, which activities could be materially delayed should we lose access to those facilities.

We have no research and development facilities of our own. As of the date of this prospectus, we are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have relied on UMDNJ for this purpose in relation to our Bioral® technology, as well as third party providers of testing and trial services. Additionally, the Universities own certain of the patents to our encochleation drug delivery technology. Our inability to conduct research and development, or our inability to find suitable third party providers of research and development services on an outsourcing basis, may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technologies, formulations and products.

We leased our research facility from UMDNJ, which lease expired December 31, 2005. We are currently leasing the space on a month to month basis, but are in negotiations to renew the lease. No assurances can be given that we will be able to enter into, extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations. Should the lease expire or if we are otherwise are required to relocate on short notice, we do not currently have an alternate facility where we could relocate. The cost and time to establish or locate an alternative research and development facility to develop our technologies, other than through the Universities, or to find suitable third party providers of research and development services on an outsourcing basis, could be substantial and might delay gaining FDA approval and commercializing our formulations and products, assuming that we have not defaulted on the terms of our intellectual property licenses and can continue with our approval process.

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We may be unable to obtain, or elect not to pursue, extensions of our NIH grants and we may not be able to secure new NIH or similar grants in the future, which could deny us important funding.

In 2001, the NIH awarded us a Small Business Innovation Research Grant, or SBIR, which we utilized in our research and development efforts relating to our Bioral® Amphotericin B formulation. We have received all anticipated funding under this grant to date, and this grant expired in August 2004. In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. This grant expired in December 2005 but was extended by the NIH in February 2006 until July 31, 2006, and we believe this will be the final extension for this grant. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ. Also, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Moreover, although we may seek additional NIH funding for either of these or other programs, we may choose not to seek such funding or such funding may be unavailable to us even should we desire it. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or other projects. Furthermore, as a result of these expirations, we incurred a decline in sponsored research revenue with associated NIH grant expenditures in 2005.

Risks Related to Our Products in Development and Regulation

Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.

Our research and development activities and the manufacture and marketing of our proposed formulations and products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

Moreover, we may never receive regulatory approval of our proposed products and formulations. No assurances can be given that we will be able to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability. For example, on February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We subsequently have had interactions with the FDA regarding Emezine®, and at the present time, given our level of resources and our focus on other initiatives, it is not likely that we will proceed with Emezine® in the foreseeable future.

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Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair the viability of our company.

In order to be commercially viable, we must research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate with our drug delivery technologies, we must meet a number of critical developmental milestones, including:

- demonstrate benefit from delivery of each specific drug through our drug delivery technologies;
- demonstrate through pre-clinical and clinical trials that our drug delivery technologies are safe and effective; and
- establish a viable Good Manufacturing Process capable of potential scale-up.

The required capital and time-frame necessary to achieve these developmental milestones is uncertain, and we may not able to achieve these milestones for any of our proposed formulations or products in development. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA s requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption without FDA approval.

Moreover, it is our stated intention to attempt to avail ourselves of the FDA s 505(b)(2) approval procedure, which we believe is less costly and time consuming. If this approval pathway is not available to us with respect to a particular formulation or product or at all, the time and cost associated with developing and commercialize such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

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We depend on technology licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher royalties.

We rely, in large part, on drug delivery technologies that we license from third parties such as the Universities, QLT and Reckitt. The loss of these licenses would seriously impair our business and future viability. After the expiration of these licenses, this technology may not continue to be available on commercially reasonable terms, if at all, and may be difficult to replace. The loss of any of these technology licenses could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we may license in the future could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

Competitors in the drug development or specialty pharmaceutical industries may develop competing technology.

Drug companies and/or other technology companies may seek to develop and market nanoencapsulation, mucosal adhesive or other technologies which may compete with our technologies. While we believe that our technologies have certain advantages over potential competitors, competitors may develop similar or different technologies which may become more accepted by the marketplace. In addition, these competitors may be larger and better financed than we are, thus giving them a significant advantage over us.

Our lead product candidates contain narcotic ingredients. The development, manufacturing and sale of such products are subject strict regulation, including the necessity of risk management programs, which may prove difficult or expensive to comply with.

Our lead product candidates, most notably BEMA Fentanyl and BEMA LA, contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. The FDA or the U.S. Drug Enforcement Administration, or DEA, currently impose and may impose additional regulations concerning the development manufacture and sale of prescription narcotics. Such regulations include labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such current or new regulations may be difficult and expensive for us to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

The DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our lead products in development, including fentanyl

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and the active ingredient in BEMA LA, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to complete clinical trials or meet commercial demand. We must annually apply to the DEA for procurement quota in order to obtain these substances. The DEA may not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. No assurance can be given that the DEA review of such materials may not result in delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

The market for our proposed formulations and products is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and proposed formulations or products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

We are engaged in the development of drug delivery technologies. As a result, our resources are limited and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our technology. Our competitors may develop drug delivery technologies and drugs that are safer, more effective or less costly than our proposed formulations or products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

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If users of our proposed formulations or products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed formulations or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

We could be exposed to significant drug liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of $2 million with a $1 million limit per occurrence which does not provide coverage for product liability for commercial products. All of our pre-clinical trials have been and all of our proposed clinical and pre-clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have insurance relating to product liability or insurance related to clinical or pre-clinical trials only with respect to our developmental product portfolio, for which we have a clinical trial liability policy providing for a $2 million aggregate limit. We intend to seek additional insurance against such risks before our product sales are commenced, although there can be no assurance that such insurance can be obtained at such time, or even if it is available, that the cost will be affordable. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. The cost and availability of such insurance are unknown. Product liability claims or other claims related to our proposed formulations and products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products.

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Our business involves environmental risks related to handling regulated substances which could severely affect our ability to conduct research and development of our drug delivery technology.

In connection with our research and development activities and our manufacture of materials and drugs, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. The current hazardous chemicals that we currently use, which may change as our research progresses, are chloroform and methanol. We are authorized to use these and other hazardous chemicals in our facilities through our affiliation with the UMDNJ. UMDNJ also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard. Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Our Management and Key Employees

We depend upon key personnel who may terminate their employment with us at any time, and we will need to hire additional qualified personnel.

Our success will depend to a significant degree upon the continued services of key management, technical, and scientific personnel, including Drs. Francis O Donnell, Mark Sirgo, Andrew Finn, Raphael Mannino and Mr. James McNulty. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain key person life insurance on the lives of our Chairman of the Board, Dr. Frank O Donnell, our President and Chief Executive Officer, Dr. Mark Sirgo, or any of our other executive officers. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Executive officers, directors and entities affiliated with them have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders.

As of the date of this prospectus, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 34.77% of our outstanding common stock. These figures do not reflect any future potential exercise of our other outstanding warrants (including those issued to Laurus, CDC and others) into shares of common stock or the increased percentages that our officers and directors may have in the event that they exercise any of the options granted to them under our Amended and Restated 2001 Stock Incentive Plan or if they otherwise acquire additional shares of common stock generally.

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The interests of our current officer and director stockholders may differ from the interests of other stockholders. As a result, these current officer and director stockholders would have the ability to exercise significant control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets and material financing transactions;

election of directors;

adoption of or amendments to stock option plans;

amendment of charter documents; or

issuance of blank check preferred stock.

Certain of our management team have relationships which may potentially result in conflicts of interests.

Dr. O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc. and Biotechnology Specialty Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. Each of these business arrangements was approved (with Dr. O Donnell abstaining) by our board of directors and our predecessor s board of directors. In addition, Dr. Mannino is a member of the board of directors of Biovest International, Inc. (OTC BB:BVTI), a subsidiary of Accentia, and Mr. McNulty is employed by Accentia. These relationships and agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and such members of our management.

Risks Related to Our Publicly-Traded Securities

Our stock price is subject to market factors, and your investment in our securities could decline in value.

Since our initial public offering in June 2002, there has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. In addition, the overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

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If we cannot meet the Nasdaq Capital Market s continuing listing requirements and Nasdaq rules, Nasdaq may delist our securities, which could negatively affect our company, the price of our securities and your ability to sell our securities.

In 2004, according to rules of the Nasdaq Capital Market (then known as the Nasdaq SmallCap Market), our shares of common stock were subject to potential delisting from such market because we did not meet certain requirements. Also, on September 15, 2005, the Nasdaq Stock Market informed us of its view that we did not meet continuing listing requirements as a result of the non-independent status of Donald L. Ferguson, a former director of our company. These issues have been resolved and we believe that we are currently in compliance with Nasdaq listing requirements. Although, as of the date of this prospectus, our shares are still listed on the Nasdaq Capital Market, in the future, we may not be able to meet the listing maintenance requirements of the Nasdaq Capital Market and Nasdaq rules, which require, among other things, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of independent directors on our board of directors. If we are unable to satisfy the Nasdaq criteria for maintaining listing, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the National Association of Securities Dealers, Inc. s electronic bulletin board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

Additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

We are authorized to issue 45 million shares of our common stock. As of June 29, 2007, there were 19,022,540 shares of common stock issued and 19,007,049 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. We will likely, subject to the approval of our stockholders, increase the size of our option plan at our next annual meeting of stockholders. To the extent such options (including options under our larger, amended option plan) or warrants are exercised, the holders of our common stock may experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution. Moreover, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5,000,000 shares of authorized preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market for our common stock.

We presently have a significant number of convertible securities outstanding, including: (i) 2,696,381 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.91 per share and (ii) 5,465,766 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.51 per share. If and when these

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securities are converted or exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that preserve our current management.

Our certificate of incorporation and by-laws may discourage, delay or prevent a change in our management team that stockholders may consider favorable. These provisions include:

- authorizing the issuance of blank check preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could allow our board of directors to affect your rights as a stockholder since our board of directors can make it more difficult for common stockholders to replace members of the board. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

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USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the 2,543,871 shares of common stock underlying the Relevant Laurus Warrants and Kashner warrant registered hereunder. If and when all of the shares underlying the warrants held by Laurus and the shares underlying the Kashner warrant are exercised, we will receive the proceeds from the exercise of those warrants and/or option. Laurus is under no obligation to exercise such warrants, and Kashner is under no obligation to exercise their warrant. If the Relevant Laurus Warrants are exercised in full, we will receive up to approximately $9,189,855. If the Kashner warrant is exercised in full, we will receive up to approximately $284,750. We expect to use such proceeds, if any, for the continued development of our products and for working capital and general corporate purposes.

SELLING STOCKHOLDERS

Up to 2,476,871 shares of common stock are being offered by this prospectus for sale by Laurus for its own account. These shares include: (i) up to 110,000 shares of our common stock issuable upon the exercise of the July 2006 Warrants issued by us to Laurus on July 31, 2006; (ii) up to 33,000 shares of our common stock issuable upon the exercise of the September 2006 Warrant issued by us to Laurus on September 20, 2006; (iii) up to 1,500,000 shares of our common stock issuable upon the exercise the December 2006 Warrants issued by us to Laurus on December 28, 2006; and (iv) up to 833,871 shares of our common stock issuable upon the exercise of the April 2007 Warrant issued by us to Laurus on April 10, 2007.

In addition, 67,000 shares of our common stock issuable upon the exercise of the Kashner warrant are offered by this prospectus for sale by Kashner and its assignees.

All proceeds of this offering will be received by the selling stockholders for their own accounts. We may receive proceeds in connection with the exercise of the Relevant Laurus Warrants and the Kashner warrant, the underlying shares associated with which may, in turn, be sold by the selling stockholders. As used in this prospectus, the term selling stockholders includes Laurus, Kashner and their respective transferees, assignees, pledgees, donees or other successors.

The following table sets forth, to our knowledge, information as of June 29, 2007 regarding beneficial ownership of our common stock by Laurus and Kashner both before and immediately after the offering. Actual common stock ownership by Laurus is subject to the exercises of the 2005 June warrants and the 2005 December warrants held by Laurus, as well as the exercise of the Relevant Laurus Warrants which underlying shares of common stock are being registered hereby. Actual ownership of common stock by Kashner is subject to the exercise of 200,000 unit purchase options to purchase a like number of shares our common stock and a like number of warrants to purchase our common stock, as well as the exercise of the option to purchase 67,000 shares of our common stock, which underlying shares are registered hereby.

Beneficial ownership is determined in accordance with Rule 13d-3 promulgated by the SEC, and generally includes voting or investment power with respect to securities. In computing the number of shares beneficially owned by the holder and the percentage ownership of the holder, shares of common stock issuable upon conversion of the notes and upon exercise of the warrant held by the holder that are currently convertible or are exercisable or convertible or exercisable within 60 days after the date of the table are deemed outstanding.

To our knowledge, Laurus has sole voting and investment power with respect to all of the shares of common stock beneficially owned by it, except that Laurus Capital Management, LLC, a Delaware limited liability company, may be deemed a control person of the shares held by Laurus. David Grin and

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Eugene Grin are the managing members of Laurus Capital Management, LLC. The address for Laurus, Laurus Capital Management, LLC and Messrs. David Grin and Eugene Grin is 825 Third Avenue, 14th Floor, New York, New York 10022. Other than with respect to the February 2005 and May 2005 financing transactions we have had with Laurus (and the related amendments thereto), Laurus has not held nor had any material relationship with us in the past three years.

To our knowledge, Kashner has sole voting and investment power with respect to all of the shares of common stock beneficially owned by it. Victor Kashner is the principal of Kashner Davidson Securities Corporation. The address for Kashner Davidson Securities Corporation is 77 South Palm Avenue, Sarasota, FL, 34236. Other than in its capacity as a consultant to us in 2004, Kashner has not held nor had any material relationship with us in the past three years. Kashner was the representative of the underwriters in connection with our June 2002 initial public offering.

The percent of beneficial ownership for the selling stockholders is based on shares of common stock outstanding as of June 29, 2007. Shares of common stock subject to warrants, options and other convertible securities that are currently exercisable or exercisable within 60 days of June 29, 2007, are considered outstanding and beneficially owned by a selling stockholder who holds those warrants, options or other convertible securities for the purpose of computing the percentage ownership of that selling stockholder but are not treated as outstanding for the purpose of computing the percentage ownership of any other stockholder.

The shares of common stock being offered under this prospectus may be offered for sale from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the account of the selling stockholders. After the date of effectiveness of the registration statement of which this prospectus is a part, the selling stockholders may have sold or transferred, in transactions covered by this prospectus or in transactions exempt from the registration requirements of the Securities Act, some or all of its common stock. Information about the selling stockholders may change over time.

Any changed information will be set forth in an amendment to the registration statement or supplement to this prospectus, to the extent required by law.

Name	Position, Office or Other Material Relationship	Number of Shares Represented by warrants, Beneficially Owned	Total Number of Shares of common stock Beneficially Owned	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering
Laurus Master Fund, Ltd. (1)	None	1,882,525	1,876,550	2,476,871	0	0
Kashner Davidson Securities Corp. (2)	None	67,000(3)	467,000	67,000	400,000	2.12%

(1) The terms of the warrants issued to Laurus, whose underlying shares of common stock are included for resale under this prospectus, provide that Laurus is not entitled to receive shares upon exercise of the warrants if such receipt would cause Laurus to be deemed to beneficially own, in the case of the April 2007 Warrant and the December 2006 Warrants, in excess of 9.99% of the outstanding shares of our

common stock on the date of issuance of such shares, and in the case of the September 2006 Warrant and the July 2006 Warrants, in excess of 4.99% of the outstanding shares of our common stock on the date of issuance of such shares, (each such

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provision may be waived by Laurus upon 75 days prior written notice to us). Therefore, based on the combined total of 2,333,871 shares underlying the April 2007 and December 2006 Warrants, Laurus is deemed to beneficially own 1,876,550 shares of our common stock, or 9.99% of our 18,790,107 shares of common stock currently outstanding.

(2) As compensation for Kashner s role as representative of the underwriters in our 2002 initial public offering, we issued them and/or their designees a unit purchase option to acquire an aggregate of 200,000 shares of our common stock and warrants to purchase 200,000 shares of our common stock. These sale of these shares of common stock was registered pursuant to our registration statement (File No. 333-72872), as amended, which was declared effective June 24, 2002.

(3) In 2004, we issued to Kashner a warrant to purchase 67,000 shares of our common stock as compensation for consulting services rendered to us.

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PLAN OF DISTRIBUTION

The selling stockholders and any of their pledges, assignees, donees selling shares received from such selling stockholders as a gift, and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales and therefore they will be subject to the prospectus delivery requirements of the Securities Act. In such event, any commissions received by such brokers-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. To our knowledge and based upon information we received from the selling stockholders: (i) the selling stockholders do not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock and (ii) the selling stockholders have not received any of the securities registered hereby as underwriting compensation. We are also not aware of any underwriting plan or agreement, underwriters or dealers compensation, or passive market making or stabilizing transactions involving the purchase or distribution of these securities.

We are required to pay all fees and expenses incident to the registration of the shares, including certain fees and disbursements of counsel to the selling stockholder. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. To the extent required, we will amend or supplement this prospectus to disclose material

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arrangements regarding the plan of distribution. To comply with the securities laws of certain jurisdictions, registered or licensed brokers or dealers may need to offer or sell the shares offered by this prospectus. The applicable rules and regulations under the Exchange Act may limit any person engaged in a distribution of the shares of common stock covered by this prospectus in its ability to engage in market activities with respect to such shares. The selling stockholder, for example, will be subject to applicable provisions of the Exchange Act and the rules and regulations under it, which provisions may limit the timing of purchases and sales of any shares of common stock by the selling stockholder.

LEGAL MATTERS

The validity of the shares of our common stock being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. On July 19, 2002, we issued Ellenoff Grossman & Schole LLP 25,000 options to purchase shares of our common stock at $7.00 per share. In 2004, we issued Ellenoff Grossman & Schole LLP 44,510 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to our 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.

EXPERTS

The financial statements as of and for each of the two years in the period ended December 31, 2006, incorporated in this prospectus by reference from our Annual Report on Form 10-KSB for the year ended December 31, 2006 have been audited by Aidman, Piser & Company, P.A., independent registered public accounting firm, as stated in their report incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this prospectus. This prospectus is part of that registration statement and does not contain all the information included in the registration statement. For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission s public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

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DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company. Our Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

BioDelivery Sciences International, Inc.

2,543,871 shares

common stock

PROSPECTUS

June 29, 2007