

# SECURITIES AND EXCHANGE COMMISSION

## FORM S-1/A

General form of registration statement for all companies including face-amount certificate companies [amend]

Filing Date: **2006-08-03**  
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([HTML Version](#) on [secdatabase.com](#))

### FILER

#### **OSIRIS THERAPEUTICS, INC.**

CIK: **1360886** | IRS No.: **710881115** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **S-1/A** | Act: **33** | File No.: **333-134037** | Film No.: **061002028**  
SIC: **2836** Biological products, (no diagnostic substances)

#### Mailing Address

*2001 ALICEANNA STREET  
BALTIMORE MD 21231-3043*

#### Business Address

*2001 ALICEANNA STREET  
BALTIMORE MD 21231-3043  
410-522-5005*

As filed with the Securities and Exchange Commission on August 3, 2006.

Registration No. 333-134037

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Amendment No. 4**  
**to**  
**Form S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**OSIRIS THERAPEUTICS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**2836**

*(Primary SIC Code Number)*

**71-0881115**

*(I.R.S. Employer Identification No.)*

**2001 Aliceanna St.  
Baltimore, Maryland 21231  
(410) 522-5005**

*(Address, including zip code, and telephone number,  
including area code, of registrant's principal  
executive offices)*

**C. Randal Mills, Ph.D.  
President and Chief Executive Officer  
2001 Aliceanna Street  
Baltimore, Maryland 21231  
(410) 522-5005**

*(Name, address, including zip code,  
and telephone number,  
including area code, of agent for service)*

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*Copies to:*

**Justin P. Klein, Esq.  
Douglas M. Fox, Esq.  
Ballard Spahr Andrews & Ingersoll, LLP  
300 East Lombard Street**

**Donald J. Murray, Esq.  
Dewey Ballantine LLP  
1301 Avenue of the Americas**

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.**

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## EXPLANATORY NOTE

The sole purpose of this amendment is to file Exhibit 1.1 to the registration statement as indicated in Item 16 and in the Exhibit Index of this amendment. No change is made to the preliminary prospectus constituting Part I of the registration statement or Items 13, 14, 15 or 17 of Part II of the registration statement. Accordingly, this amendment consists only of the facing page, this explanatory note, Item 16, the signature page to the registration statement, the Exhibit Index of the registration statement, and Exhibit 1.1.

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## Item 16. Exhibits and Financial Statement Schedules

### (a) Exhibits

Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement.
3.1†	Form of Amended and Restated Certificate of Incorporation of the Registrant to be effective upon consummation of this offering.
3.2†	Form of Amended and Restated Bylaws of the Registrant to be effective upon consummation of this offering.
4.1†	Form of Common Stock Certificate.
5.1†	Opinion of Ballard Spahr Andrews & Ingersoll, LLP, counsel to the Registrant, with respect to the legality of the securities being registered.
10.1†	Amended and Restated 1994 Stock Incentive Plan, as amended.
10.2†	2006 Omnibus Plan.
10.3†	Director Compensation Policy.
10.4†	Employment Agreement by and between the Registrant and C. Randal Mills, Ph.D., dated as of May 15, 2004.
10.5†	Employment Agreement by and between the Registrant and Cary J. Claiborne, dated as of December 3, 2004.
10.6†	Employment Agreement by and between the Registrant and Harry Carmitchel, dated as of September 1, 2004.
10.7†	Employment Agreement by and between the Registrant and Earl R. Fender, dated as of June 12, 2006.
10.8†	Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003, as amended.
10.9†	Amendment No. 1 to the Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 12, 2004.
10.10†	Security Agreement from the Registrant to Boston Scientific Corporation, dated as of March 12, 2004.
10.11†	Contract Manufacturing Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.12†	Development Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.13†	Investment Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.14†	Investor Rights Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.15†	License Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.16†	Investor Rights Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.17†	License Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.18†	Distribution and Supply Agreement by and between the Registrant and Blackstone Medical, Inc., dated as of November 10, 2005.
10.19†	Technology Transfer and License Agreement by and between the Registrant and Case Western University, dated as of January 1, 1993, as amended.



- 10.20† Marketing Collaboration and License Agreement by and between the Registrant and BioWhittaker, Inc., dated as of August 11, 1999.
- 10.21† Registration Rights Agreement by and between the Registrant and Cambrex Corporation, dated November 28, 2005.
- 10.22† Form of \$20.6 Million Convertible Promissory Note.
- 10.23† Lease Agreement by and between the Registrant and SAGA Limited Partnership, dated as of January 18, 1995, as amended.
- 10.24† Second Amended and Restated Sublease Agreement by and between the Registrant and Maryland Economic Development Corporation, dated as of June 30, 1998, as amended.
- 10.25† Lease Agreement by and between Gateway S-8, LLLP and Nova Telecommunications, Inc., dated August 11, 1998, as amended.
- 10.26† Sublease Agreement by and between the Registrant and Broadwing Corporation, dated as of June 2, 2006.
- 10.27† Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated June 6, 2006.
- 10.28† Consulting Agreement by and between the Registrant and Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, dated November 1995, as amended.
- 10.29† Termination Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, to the Registrant, dated May 10, 2006.
- 10.30† Indemnification Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, and Peter Friedli to the Registrant, dated May 19, 2006.
- 10.31† Warrant to Purchase up to 4,000,000 shares of Common Stock granted by Registrant to Peter Friedli, dated May 24, 2006.
- 10.32† Form of Registration Rights Agreement in connection with the \$20.6 million Convertible Promissory Note.
- 10.33† Form of \$2.0 million Convertible Promissory Note Maturing September 20, 2008.
- 10.34† Form of Convertible Promissory Note Maturing March 30, 2008.
- 10.35† Form of Convertible Promissory Note Maturing June 10, 2008.
- 10.36† Employment Agreement by and between the Registrant and Lode Debrabandere, dated as of July 31, 2006.
- 23.1† Consent of Stegman & Company.
- 23.2† Consent of Ballard Spahr Andrews & Ingersoll, LLP (see Exhibit 5.1).
- 99.1† Consent of Jay Moyes.
- 99.2† Consent of Gregory H. Barnhill.
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† Previously filed.

\*\* Confidential treatment has been requested for portions of this exhibit.

*(b) Financial Statement Schedules*

Financial Statement Schedules are omitted because the information is included in our financial statements or notes to those financial statements.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 4 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Baltimore, State of Maryland, on the 3rd day of August 2006.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 4 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ C. RANDAL MILLS</u> C. Randal Mills	Chief Executive Officer and Director (Principal Executive Officer)	August 3, 2006
<u>/s/ CARY J. CLAIBORNE</u> Cary J. Claiborne	Chief Financial Officer (Principal Financial Officer)	August 3, 2006
<u>/s/ C. RANDAL MILLS</u> Peter Friedli by C. Randal Mills, Attorney-in-fact	Director	August 3, 2006
<u>/s/ C. RANDAL MILLS</u> Felix Gutzwiller by C. Randal Mills, Attorney-in-fact	Director	August 3, 2006
<u>/s/ PHILIP R. JACOBY, JR.</u> Philip R. Jacoby, Jr.	Corporate Controller (Chief Accounting Officer)	August 3, 2006



## EXHIBIT INDEX

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† Previously filed.

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QuickLinks

[EXPLANATORY NOTE](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

3,500,000 Shares

Osiris Therapeutics, Inc.

Common Stock

(\$0.001 Par Value)

EQUITY UNDERWRITING AGREEMENT

August 3, 2005

Jefferies & Company, Inc.  
Lazard Capital Market LLC  
Leerink Swann & Co.

As Representatives of the Several Underwriters

c/o Jefferies & Company, Inc.  
520 Madison Avenue  
New York, New York 10022

Ladies and Gentlemen:

Osiris Therapeutics, Inc., a Delaware corporation (the "Company"), proposes to sell to the several underwriters (the "Underwriters") named in Schedule I hereto for whom you are acting as Representatives (the "Representatives") an aggregate of 3,500,000 shares (the "Firm Shares") of the Company's common stock, \$0.001 par value (the "Common Stock"). The respective amounts of the Firm Shares to be so purchased by the several Underwriters are set forth opposite their names in Schedule I hereto. The Company also proposes to sell at the Underwriters' option an aggregate of up to 525,000 additional shares of the Company's Common Stock (the "Option Shares") as set forth below.

As the Representatives, you have advised the Company (a) that you are authorized to enter into this Agreement on behalf of the several Underwriters, and (b) that the several Underwriters are willing, acting severally and not jointly, to purchase the numbers of Firm Shares set forth opposite their respective names in Schedule I, plus their pro rata portion of the Option Shares if you elect to exercise the over-allotment option in whole or in part for the accounts of the several Underwriters. The Firm Shares and the Option Shares (to the extent the aforementioned option is exercised) are herein collectively called the "Shares."

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In consideration of the mutual agreements contained herein and of the interests of the parties in the transactions contemplated hereby, the parties hereto agree as follows:

1. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

(a) A registration statement on Form S-1 (File No. 333-134037) with respect to the Shares has been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the “Act”), and the rules and regulations (the “Rules and Regulations”) of the Securities and Exchange Commission (the “Commission”) thereunder and has been filed with the Commission. Copies of such registration statement, including any amendments thereto, the preliminary prospectuses (meeting the requirements of the Rules and Regulations) contained therein and the exhibits, financial statements and schedules, as finally amended and revised, have heretofore been delivered by the Company to you. Such registration statement, together with any registration statement filed by the Company pursuant to Rule 462(b) under the Act, is herein referred to as the “Registration Statement,” which shall be deemed to include all information omitted therefrom in reliance upon Rules 430A, 430B or 430C under the Act and contained in the Prospectus referred to below, has become effective under the Act and no post-effective amendment to the Registration Statement has been filed as of the date of this Agreement. “Prospectus” means the form of prospectus first filed with the Commission pursuant to and within the time limits described in Rule 424(b) under the Act. Each preliminary prospectus included in the Registration Statement prior to the time it becomes effective is herein referred to as a “Preliminary Prospectus.”

(b) As of the Applicable Time (as defined below) and as of the Closing Date or the Option Closing Date, as the case may be, neither (i) the General Use Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time, the Statutory Prospectus (as defined below), and the information included on Schedule II hereto, all considered together (collectively, the “General Disclosure Package”), nor (ii) any individual Limited Use Free Writing Prospectus (as defined below), when considered together with the General Disclosure Package, included or will include any untrue statement of a material fact or omitted or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading provided, however, that the Company makes no representations or warranties as to information contained in or omitted from any Issuer Free Writing Prospectus, in reliance upon, and in conformity with, written information furnished to the Company by or on behalf of any Underwriter through the Representatives, specifically for use therein, it being understood and agreed that the only such information is that described in Section 13 herein. As used in this subsection and elsewhere in this Agreement:

“Applicable Time” means \_\_\_\_\_ pm (New York time) on the date of this Agreement or such other time as agreed to by the Company and the Representatives.

“Statutory Prospectus” as of any time means the Preliminary Prospectus relating to the Shares that is included in the Registration Statement immediately prior to that time.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433 under the Act, relating to the Shares in the form filed or required to be filed with the

Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g) under the Act.

“General Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is identified on Schedule III to this Agreement.

“Limited Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is not a General Use Free Writing Prospectus.

(c) The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware, with corporate power and authority to own or lease its properties and conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus. The only subsidiary of the Company is Gryphon Pharmaceuticals, Inc., a Delaware corporation (the “Subsidiary”). The Subsidiary fails to validly exist as a corporation in good standing under the laws of the jurisdiction of its incorporation, which such failure does not have a Material Adverse Effect (as hereinafter defined). The Subsidiary does not own any assets or property or possess any rights, licenses, franchises or permits, have any liabilities or conduct any operations that are, individually or in the aggregate, material to the Company. The Company and the Subsidiary are duly qualified to transact business in all jurisdictions in which the conduct of their business requires such qualification. The only jurisdiction in which the Company is required to qualify to transact business is the State of Maryland, and the Company is so qualified in such state. The outstanding shares of capital stock of the Subsidiary have been duly authorized and validly issued, are

fully paid and non-assessable and are owned by the Company free and clear of all liens, encumbrances and equities and claims; and no options, warrants or other rights to purchase, agreements or other obligations to issue or other rights to convert any obligations into shares of capital stock or ownership interests in the Subsidiary are outstanding.

(d) The outstanding shares of Common Stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable; the Shares to be issued and sold by the Company have been duly authorized and when issued and paid for as contemplated herein will be validly issued, fully paid and non-assessable; and (i) except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, no person has the right, contractual or otherwise, to cause the Company to issue or sell to it any shares of Common Stock or shares of any other capital stock or other equity interests of the Company, (ii) no person has any preemptive rights, resale rights, rights of first refusal or other rights to purchase any shares of Common Stock or shares of any other capital stock of or other equity interests in the Company, except to the extent validly waived, and (iii) no person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Shares; and (iv) no person has the right, contractual or otherwise, to cause the Company to register under the Act any shares of Common Stock or shares of any other capital stock of or other equity interests in the Company, or to include any such shares or interests in the Registration Statement or the offering contemplated thereby, which rights have not been validly waived.

(e) The information set forth under the caption "Capitalization" in the Registration Statement and the Prospectus (and any similar section or information contained in the General Disclosure Package) is true and correct. All of the Shares conform to the description thereof contained in the Registration Statement, the General Disclosure Package and the Prospectus. The form of certificates for the Shares conforms to the Delaware General Corporation Law.

(f) The Commission has not issued an order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus relating to the proposed offering of the Shares, and no proceeding for that purpose or pursuant to Section 8A of the Act has been instituted or, to the Company's knowledge, threatened by the Commission. The Registration Statement contains, and the Prospectus and any amendments or supplements thereto will contain, all statements which are required to be stated therein by, and will conform to, the requirements of the Act and the Rules and Regulations. The Registration Statement and any amendment thereto do not contain, and will not contain, any untrue statement of a material fact and do not omit, and will not omit, to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendments and supplements thereto do not contain, and will not contain, any untrue statement of a material fact; and do not omit, and will not omit, to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representations or warranties as to information contained in or omitted from the Registration Statement or the Prospectus, or any such amendment or supplement, in reliance upon, and in conformity with, written information furnished to the Company by or on behalf of any Underwriter through the Representatives, specifically for use therein, it being understood and agreed that the only such information is that described in Section 13 herein.

(g) Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Shares or until any earlier date that the Company notified or notifies the Representatives that such Issuer Free Writing Prospectus may no longer be used, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus.

(h) The Company has not, directly or indirectly, distributed and will not distribute any offering material in connection with the offering and sale of the Shares other than any Preliminary Prospectus, the Prospectus and other materials, if any, permitted under the Act and consistent with Section 4(b) below. The Company will file with the Commission all Issuer Free Writing Prospectuses in the time required under Rule 433(d) under the Act. The Company has satisfied or will satisfy the conditions in Rule 433 under the Act to avoid a requirement to file with the Commission any electronic road show.



(i) (i) At the time of initial filing the Registration Statement and (ii) as of the date hereof (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an “ineligible issuer” (as defined in Rule 405 under the Act, without taking into account any determination by the Commission pursuant to Rule 405 under the Act that it is not necessary that the Company be considered an ineligible issuer), including, without limitation, for purposes of Rules 164 and 433 under the Act with respect to the offering of the Shares as contemplated by the Registration Statement.

4

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(j) The consolidated financial statements of the Company and the Subsidiary, together with related notes and schedules as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, present fairly the financial position and the results of operations and cash flows of the Company and the Subsidiary, at the indicated dates and for the indicated periods. Such financial statements and related schedules have been prepared in accordance with generally accepted principles of accounting (“GAAP”), consistently applied throughout the periods involved, except as disclosed therein, and all adjustments necessary for a fair presentation of results for such periods have been made. The summary and selected consolidated financial and statistical data included in the Registration Statement, the General Disclosure Package and the Prospectus presents fairly the information shown therein and such data has been compiled on a basis consistent with the financial statements presented therein and the books and records of the Company. The pro forma financial statements and other pro forma financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly the information shown therein, have been prepared in accordance with the Commission’s rules and guidelines with respect to pro forma financial statements, have been properly compiled on the pro forma bases described therein, and, in the opinion of the Company, the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions or circumstances referred to therein. All disclosures contained in the Registration Statement, the General Disclosure Package and the Prospectus regarding “non-GAAP financial measures” (as such term is defined by the Rules and Regulations) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Act, to the extent applicable. The Company and the Subsidiary do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations or any “variable interest entities” within the meaning of Financial Accounting Standards Board Interpretation No. 46), not disclosed in the Registration Statement, the General Disclosure Package and the Prospectus. There are no financial statements (historical or pro forma) that are required to be included in the Registration Statement, the General Disclosure Package or the Prospectus that are not included as required.

(k) Stegman & Company PC, who have certified certain of the financial statements filed with the Commission as part of the Registration Statement, the General Disclosure Package and the Prospectus, is an independent registered public accounting firm with respect to the Company and the Subsidiary within the meaning of the Act and the applicable Rules and Regulations and the Public Company Accounting Oversight Board (United States) (the “PCAOB”).

(l) Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is not aware of (i) any material weakness in its internal control over financial reporting or (ii) change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

(m) Solely to the extent that the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated by the Commission and the Nasdaq National Market thereunder (the “Sarbanes-Oxley Act”) has been applicable to the Company, there is and has been no failure on the part of the Company to comply in all material respects with any provision

5

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of the Sarbanes-Oxley Act. The Company has taken all necessary actions to ensure that it is in compliance with all provisions of the Sarbanes-Oxley Act that are in effect and with which the Company is required to comply and is actively taking steps to ensure that it will be in compliance with other provisions of the Sarbanes-Oxley Act not currently in effect or which will become applicable to the Company.

(n) There is no action, suit, claim or proceeding pending or, to the knowledge of the Company, threatened against the Company or the Subsidiary before any court or administrative agency or otherwise which if determined adversely to the Company or the Subsidiary would either (i) have, individually or in the aggregate, a material adverse effect on the earnings, business, management, properties, assets, rights, operations, condition (financial or otherwise) or prospects of the Company and of the Subsidiary taken as a whole or (ii) prevent the consummation of the transactions contemplated hereby (the occurrence of any such effect or any such prevention described in the foregoing clauses (i) and (ii) being referred to as a "Material Adverse Effect"), except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus.

(o) The Company and the Subsidiary have good and marketable title to all of the properties and assets reflected in the consolidated financial statements hereinabove described or described in the Registration Statement, the General Disclosure Package and the Prospectus, subject to no lien, mortgage, pledge, charge or encumbrance of any kind except those reflected in such financial statements or described in the Registration Statement, the General Disclosure Package and the Prospectus or those that would not, individually or in the aggregate, have a Material Adverse Effect. The Company and the Subsidiary occupy their leased properties under valid and binding leases conforming in all material respects to the description thereof set forth in the Registration Statement, the General Disclosure Package and the Prospectus.

(p) The Company and the Subsidiary have filed all Federal, State, local and foreign tax returns which have been required to be filed and have paid all taxes indicated by such returns and all assessments received by them or any of them to the extent that such taxes have become due. All tax liabilities have been adequately provided for in the financial statements of the Company, and the Company does not know of any actual or proposed additional material tax assessments.

(q) Since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package and the Prospectus, as each may be amended or supplemented, there has not been any material adverse change or any development involving a prospective material adverse change in the earnings, business, management, properties, assets, rights, operations, condition (financial or otherwise), or prospects of the Company and the Subsidiary taken as a whole, whether or not occurring in the ordinary course of business, and there has not been any material transaction entered into or any material transaction that is probable of being entered into by the Company or the Subsidiary, other than transactions in the ordinary course of business and changes and transactions described in the Registration Statement, the General Disclosure Package and the Prospectus, as each may be amended or supplemented. Neither the Company nor the Subsidiary has any material contingent obligations which are not disclosed in the Company's financial statements which are included in the Registration Statement, the General Disclosure Package and the Prospectus.

(r) Neither the Company nor the Subsidiary is or with the giving of notice or lapse of time or both, will be, (i) in violation of its certificate or articles of incorporation, by-laws, certificate of formation, limited liability agreement, partnership agreement or other organizational documents or (ii) in violation of or in default under any agreement, lease, contract, indenture or other instrument or obligation to which it is a party or by which it, or any of its properties, is bound and, solely with respect to this clause (ii), which violation or default would have a Material Adverse Effect. The execution and delivery of this Agreement and the consummation of the transactions herein contemplated and the fulfillment of the terms hereof will not conflict with or result in a breach of any of the terms or provisions of, or constitute a default under, (A) any indenture, mortgage, deed of trust or other agreement or instrument to which the Company or the Subsidiary is a party or by which the Company or the Subsidiary or any of their respective properties is bound, (B) the certificate or articles of incorporation or by-laws of the Company or (C) any law, order, rule or regulation judgment, order, writ or decree applicable to the Company or the Subsidiary of any court or of any government, regulatory body or administrative agency or other governmental body having jurisdiction, except, in the case of clause (A) above, for any conflict, breach or default as would not, individually or in the aggregate, have a Material Adverse Effect.

(s) The execution and delivery of, and the performance by the Company of its obligations under, this Agreement has been duly and validly authorized by all necessary corporate action on the part of the Company, and this Agreement has been duly executed and delivered by the Company.

(t) Each approval, consent, order, authorization, designation, declaration or filing by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated (except such additional steps as may be required by the Commission, the National Association of Securities Dealers, Inc. (the "NASD") or such additional steps as may be necessary to qualify the Shares for public offering by the Underwriters under state securities or Blue Sky laws) has been obtained or made and is in full force and effect.

(u) the Company owns, or has obtained valid and enforceable licenses for, or other rights to use, the inventions, patent applications, patents, trademarks (both registered and unregistered), tradenames, service names, copyrights, trade secrets and other proprietary information described in the Registration Statement, the General Disclosure Package and the Prospectus, as being owned or licensed by the Company or the Subsidiary or, to the Company's knowledge, which are necessary for the conduct of their respective businesses as currently conducted or as proposed to be conducted (including the commercialization of products or services described in the Registration Statement, the General Disclosure Package and the Prospectus, if any, as under development), except where the failure to own, license or have such rights would not, individually or in the aggregate, have a Material Adverse Effect (collectively, "Intellectual Property"); (i) there are no third parties who have or, to the Company's knowledge, will be able to establish rights to any Intellectual Property, except for, and to the extent of, the ownership rights of the owners of the Intellectual Property which the Registration Statement (excluding the exhibits thereto), each Preliminary Prospectus and the Prospectus disclose is licensed to the Company; (ii) the Company has no knowledge of any infringement by third

parties of any Intellectual Property; (iii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (iv) except as described in the Registration Statement, the General Disclosure Package and the Prospectus, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts capable of forming a reasonable basis for any such action, suit, proceeding or claim, which, if asserted against the Company, would in the judgment of the Company be likely to prevail; (v) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that either the Company or the Subsidiary infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the General Disclosure Package and the Prospectus if any, as under development, infringe or violate, any patent, trademark, tradename, service name, copyright, trade secret or other proprietary rights of others, and, except as described in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (vi) the Company has complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect; (vii) to the Company's knowledge there is no material prior art that may render any pending U.S. patent application within the Intellectual Property unpatentable that has not been disclosed to the U.S. Patent and Trademark Office; and (viii) the product candidates described in the Registration Statement, the General Disclosure Package and the Prospectus, as under development by the Company fall within the scope of the claims of one or more patents owned by, or exclusively licensed to, the Company;

(v) Neither the Company, nor to the Company's knowledge, any of its affiliates, has taken or may take, directly or indirectly, any action designed to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the shares of Common Stock to facilitate the sale or resale of the Shares.

(w) Neither the Company nor the Subsidiary is or, after giving effect to the offering and sale of the Shares contemplated hereunder and the application of the net proceeds from such sale as described in the Properties, will be an "investment company" within the meaning of such term under the Investment Company Act of 1940 as amended (the "1940 Act"), and the rules and regulations of the Commission thereunder.

(x) The Company maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(y) The Company has established and maintains "disclosure controls and procedures" (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act); the Company's "disclosure controls and procedures" are reasonably designed to ensure that all information (both financial and non-financial) required to be disclosed by the Company in the reports that it files (or will file) or submits (or will submit) under the Exchange Act after the effectiveness of the Registration Statement is recorded, processed, summarized and reported within the time periods specified in the rules and regulations of the Exchange Act, and that all such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure and to make the certifications of the Chief Executive Officer and Chief Financial Officer of the Company required under the Exchange Act with respect to such reports.

(z) The statistical, industry-related and market-related data included in the Registration Statement, the General Disclosure Package and the Prospectus are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate, and such data agree with the sources from which they are derived.

(aa) The operations of the Company and the Subsidiary are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the Company's knowledge, threatened.

(bb) Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(cc) The Company and the Subsidiary carry, or are covered by, insurance in such amounts and covering such risks as is adequate for the conduct of their respective businesses and the value of their respective properties and as is customary for companies engaged in similar businesses.

(dd) The Company and the Subsidiary are in compliance in all material respects with all presently applicable provisions of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"); no "reportable event" (as defined in ERISA) has occurred with respect to any "pension plan" (as defined in ERISA) for which the Company and the Subsidiary would have any liability; neither the Company nor the Subsidiary has incurred, and the Company does not expect that either will incur, any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any

“pension plan” or (ii) Sections 412 or 4971 of the Internal Revenue Code of 1986, as amended, including the regulations and published interpretations thereunder (the “Code”); and each “pension plan” for which the Company or the Subsidiary would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(ee) To the Company’s knowledge, there are no affiliations or associations between any member of the NASD and any of the Company’s officers, directors or 5% or greater securityholders, except as set forth in the Registration Statement.

(ff) The Shares have been approved for listing subject to notice of issuance on the Nasdaq National Market.

(gg) There are no relationships or related-party transactions involving the Company or the Subsidiary or any other person required to be described in the Prospectus which have not been described as required.

(hh) Neither the Company nor the Subsidiary has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law which violation is required to be disclosed in the Prospectus.

(ii) The Company and the Subsidiary and their respective properties, assets and operations are in compliance with, and the Company holds all permits, authorizations and approvals required under, Environmental Laws (as defined below), except to the extent that failure to so comply or to hold such permits, authorizations or approvals would not, individually or in the aggregate, have a Material Adverse Effect; there are no past, present or, to the Company’s knowledge, reasonably anticipated future events, conditions, circumstances, activities, practices, actions, omissions or plans that could reasonably be expected to give rise to any material costs or liabilities to the Company or the Subsidiary under, or to interfere with or prevent compliance by the Company with, Environmental Laws; except as would not, individually or in the aggregate, have a Material Adverse Effect, neither the Company nor the Subsidiary (i) is the subject of any investigation, (ii) has received any notice or claim, (iii) is a party to or affected by any pending or, to the Company’s knowledge, threatened action, suit or proceeding, (iv) is bound by any judgment, decree or order or (v) has entered into any agreement, in each case relating to any alleged violation of any Environmental Law or any actual or alleged release or threatened release or cleanup at any location of any Hazardous Materials (as defined below) (as used herein, “Environmental Law” means any federal, state, local or foreign law, statute, ordinance, rule, regulation, order, decree, judgment, injunction, permit, license, authorization or other binding requirement, or common law, relating to health, safety or the protection, cleanup or restoration of the environment or natural resources, including those relating to the distribution, processing, generation, treatment, storage, disposal, transportation, other handling or release or threatened release of Hazardous Materials, and “Hazardous Materials” means any material (including, without limitation, pollutants, contaminants, hazardous or toxic substances or wastes) that is regulated by or may give rise to liability under any Environmental Law);

(jj) in the ordinary course of its business, the Company conducts periodic reviews of the effect of the Environmental Laws on the Company’s and the Subsidiary’s respective businesses, operations and properties, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for cleanup, closure of properties or compliance with the Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties);

(kk) the preclinical tests and clinical trials that are described in, or the results of which are referred to in, Registration Statement, the General Disclosure Package and the Prospectus, were and, if still pending, are being conducted in all material respects in accordance with protocols filed with the appropriate regulatory authorities for each such test or trial, as the case may be, and with standard medical and scientific research procedures; each description of the results of such tests and trials contained in the Registration Statement, the Preliminary Prospectuses, the Prospectus and the Permitted Free Writing Prospectuses, if any, is accurate and complete in all material respects and fairly presents the data derived from such tests and trials, and the Company has no knowledge of any other studies or tests the results of which are inconsistent with, or otherwise call into question, the results described or referred to in Registration Statement, the General Disclosure

Package and the Prospectus; neither the Company nor the Subsidiary has received any notices or other correspondence from the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency (collectively, the “Regulatory Agencies”) requiring the termination, suspension or modification of any clinical trials that are described or referred to in Registration Statement, the General Disclosure Package and the Prospectus; and the Company has operated and is currently in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies;

2. PURCHASE, SALE AND DELIVERY OF THE FIRM SHARES.

(a) On the basis of the representations, warranties and covenants herein contained, and subject to the conditions herein set forth, the Company agrees to sell to the Underwriters and each Underwriter agrees, severally and not jointly, to purchase, at a price of \$ \_\_\_\_ per share, the number of Firm Shares set forth opposite the name of each Underwriter in Schedule I hereof, subject to adjustments in accordance with Section 9 hereof.

(b) Payment for the Firm Shares to be sold hereunder is to be made in Federal (same day) funds against delivery of certificates therefor to the Representatives for the several accounts of the Underwriters. Such payment and delivery are to be made through the facilities of The Depository Trust Company, New York, New York at 10:00 a.m., New York time, on the third business day after the date of this Agreement or at such other time and date not later than five business days thereafter as you and the Company shall agree upon, such time and date being herein referred to as the “Closing Date.” (As used herein, “business day” means a day on which the New York Stock Exchange is open for trading and on which banks in New York are open for business and are not permitted by law or executive order to be closed.)

(c) In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase the Option Shares at the price per share as set forth in the first paragraph of this Section 2. The option granted hereby may be exercised in whole or in part by giving written notice (i) at any time before the Closing Date and (ii) only once thereafter within 30 days after the date of this Agreement, by you, as Representatives of the several Underwriters, to the Company setting forth the number of Option Shares as to which the several Underwriters are exercising the option and the time and date at which such certificates are to be delivered. The time and date at which certificates for Option Shares are to be delivered shall be determined by the Representatives but shall not be earlier than three nor later than 10 full business days after the exercise of such option, nor in any event prior to the Closing Date (such time and date being herein referred to as the “Option Closing Date”). If the date of exercise of the option is three or more days before the Closing Date, the notice of exercise shall set the Closing Date as the Option Closing Date. The number of Option Shares to be purchased by each Underwriter shall be in the same proportion to the total number of Option Shares being purchased as the number of Firm Shares being purchased by such Underwriter bears to the total number of Firm Shares, adjusted by you in such manner as to avoid fractional shares. The option with respect to the Option Shares granted hereunder may be exercised only to cover over-allotments in the sale of the Firm Shares by the Underwriters. You, as Representatives of the several Underwriters, may cancel such option at any time prior to its expiration by giving written notice of such cancellation to the Company. To the extent, if any, that the option is exercised, payment for the Option Shares shall be made on the Option Closing Date in Federal (same day funds) through the facilities of The Depository Trust Company in New York, New York drawn to the order of the Company.

3. OFFERING BY THE UNDERWRITERS.

It is understood that the several Underwriters are to make a public offering of the Firm Shares as soon as the Representatives deems it advisable to do so. The Firm Shares are to be initially offered to the public at the initial public offering price set forth in the Prospectus. The Representatives may from time to time thereafter change the public offering price and other selling terms.

It is further understood that you will act as the Representatives for the Underwriters in the offering and sale of the Shares in accordance with a Master Agreement Among Underwriters entered into by you and the several other Underwriters.

4. COVENANTS OF THE COMPANY.

(a) The Company will (i) prepare and timely file with the Commission under Rule 424(b) under the Act a Prospectus in a form approved by the Representatives containing information previously omitted at the time of effectiveness of the Registration Statement in reliance on Rules 430A, 430B or 430C under the Act and (ii) not file any amendment to the Registration Statement or distribute an amendment or supplement to the General Disclosure Package or the Prospectus of which the Representatives shall not previously have been advised and furnished with

a copy or to which the Representatives shall have reasonably objected in writing or which is not in compliance with the Rules and Regulations.

(b) The Company will (i) not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus” (as defined in Rule 405 under the Act) required to be filed by the Company with the Commission under Rule 433 under the Act unless the Representatives approves its use in writing prior to first use (each, a “Permitted Free Writing Prospectus”); provided that the prior written consent of the Representatives hereto shall be deemed to have been given in respect of the Issuer Free Writing Prospectus(es) included in Schedule III hereto, (ii) treat each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, (iii) comply with the requirements of Rules 164 and 433 under the Act applicable to any Issuer Free Writing Prospectus, including the requirements relating to timely filing with the Commission, legending and record keeping and (iv) not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Act a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder. The Company will satisfy the conditions in Rule 433 under the Act to avoid a requirement to file with the Commission any electronic road show.

(c) The Company will advise the Representatives promptly (i) when the Registration Statement or any post-effective amendment thereto shall have become effective, (ii) of receipt of any comments from the Commission, (iii) of any request of the Commission for amendment of the Registration Statement or for supplement to the General Disclosure Package or the Prospectus or for any additional information, and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus, or of the institution of any proceedings for that purpose or pursuant to Section 8A of the Act. The Company will use its best efforts to prevent the issuance of any such order and to obtain as soon as possible the lifting thereof, if issued.

(d) The Company will cooperate with the Representatives in endeavoring to qualify the Shares for sale under the securities laws of such jurisdictions as the Representatives may reasonably have designated in writing and will make such applications, file such documents, and furnish such information as may be reasonably required for that purpose, provided the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction where it is not now so qualified or required to file such a consent. The Company will, from time to time, prepare and file such statements, reports, and other documents, as are or may be required to continue such qualifications in effect for so long a period as the Representatives may reasonably request for distribution of the Shares.

(e) The Company will deliver to, or upon the order of, the Representatives, from time to time, as many copies of any Preliminary Prospectus as the Representatives may reasonably request. The Company will deliver to, or upon the order of, the Representatives, from time to time, as many copies of any Issuer Free Writing Prospectus as the Representatives may reasonably request. The Company will deliver to, or upon the order of, the Representatives during the period when delivery of a Prospectus (or, in lieu thereof, the notice referred to under Rule 173(a) under the

Act) (the "Prospectus Delivery Period") is required under the Act, as many copies of the Prospectus in final form, or as thereafter amended or supplemented, as the Representatives may reasonably request. The Company will deliver to the Representatives at or before the Closing Date, four signed copies of the Registration Statement and all amendments thereto including all exhibits filed therewith, and will deliver to the Representatives such number of copies of the Registration Statement (including such number of copies of the exhibits filed therewith that may reasonably be requested), and of all amendments thereto, as the Representatives may reasonably request.

(f) The Company will comply with the Act and the Rules and Regulations, and the Exchange Act, and the rules and regulations of the Commission thereunder, so as to permit the completion of the distribution of the Shares as contemplated in this Agreement and the Prospectus. If during the period in which a prospectus (or, in lieu thereof, the notice referred to under Rule 173(a) under the Act) is required by law to be delivered by an Underwriter or dealer, any event shall occur as a result of which, in the judgment of the Company or in the reasonable opinion of the Underwriters, it becomes necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances existing at the time the Prospectus is delivered to a purchaser, not misleading, or, if it is necessary at any time to amend or supplement the Prospectus to comply with any law, the Company promptly will prepare and file with the Commission an appropriate amendment to the Registration Statement or supplement to the Prospectus so that the Prospectus as so amended or supplemented will not, in the light of the circumstances when it is so delivered, be misleading, or so that the Prospectus will comply with the law.

(g) If the General Disclosure Package is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur as a result of which, in the judgment of the Company or in the reasonable opinion of the Underwriters, it becomes necessary to amend or supplement the General Disclosure Package in order to make the statements therein, in the light of the circumstances, not misleading, or to make the statements therein not conflict with the information contained in the Registration Statement then on file, or if it is necessary at any time to amend or supplement the General Disclosure Package to comply with any law, the Company promptly will prepare, file with the Commission (if required) and furnish to the Underwriters and any dealers an appropriate amendment or supplement to the General Disclosure Package so that the statements made in the General Disclosure Package as so amended or supplemented will not, in the light of the circumstances under which they were made, be misleading or conflict with the Registration Statement then on file, or so that the General Disclosure Package will comply with law.

(h) The Company will make generally available to its security holders, as soon as it is practicable to do so, but in any event not later than 15 months after the effective date of the Registration Statement, an earnings statement (which need not be audited) in reasonable detail, covering a period of at least 12 consecutive months beginning after the effective date of the Registration Statement, which earnings statement shall satisfy the requirements of Section 11(a) of the Act and Rule 158 under the Act and will advise you in writing when such statement has been so made available.

(i) Prior to the Closing Date, the Company will furnish to the Underwriters, as soon as they have been prepared by or are available to the Company, a copy of any unaudited interim financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

(j) No offering, sale, short sale or other disposition of any shares of Common Stock of the Company or other securities convertible into or exchangeable or exercisable for shares of Common Stock or derivative of Common Stock (or agreement for such) will be made for a period of 180 days after the date of the Prospectus, directly or indirectly, by the Company otherwise than hereunder or with the prior written consent of Jefferies & Company, Inc., as Representatives ("Jefferies"). Notwithstanding the foregoing, if (i) during the last 17 days of the 180-day restricted period, the Company issues an earnings release or material news or a material event relating to the Company occurs; or (ii) prior to the expiration of the 180-day restricted period, the Company announces that it will release earnings results during the 16-day period following the last day of the 180-day restricted period, then in each case the restrictions imposed by this Agreement shall continue to apply until the expiration of



the 18-day period beginning on the date of the release of the earnings results or the occurrence of material news or a material event relating to the Company, as the case may be, unless Jefferies waives, in writing, such extension.

(k) The Company has caused each officer and director of the Company, and the holders of at least 96% of the outstanding shares of Common Stock (treating, for all purposes of this Section 4(l), all options or warrants or other securities exercisable or exchangeable for Common Stock as having been exercised or exchanged (as the case may be) and all securities convertible into Common Stock as having been converted), to furnish to you, on or prior to the date of this agreement, a letter or letters, substantially in the form attached hereto as Exhibit A (the "Lockup Agreement").

(l) The Company shall apply the net proceeds of its sale of the Shares as set forth in the Registration Statement, General Disclosure Package and the Prospectus and shall file such reports with the Commission with respect to the sale of the Shares and the application of the proceeds therefrom as may be required in accordance with Rule 463 under the Act.

(m) The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or the Subsidiary to register as an investment company under the 1940 Act.

(n) The Company will maintain a transfer agent and, if necessary under the jurisdiction of incorporation of the Company, a registrar for the Common Stock.

(o) The Company will not take, directly or indirectly, any action designed to cause or result in, or that has constituted or might reasonably be expected to constitute, the stabilization or manipulation of the price of any securities of the Company.

(p) Upon the written request of Jefferies & Company, Inc. or any Underwriter, the Company shall (i) furnish to Jefferies & Company, Inc. or such other Underwriter, a certification, as contemplated by and in compliance with Treasury regulations Section 1.897-

2(h), that as of any Closing Date (or such other date as may be specified in such request), the Shares are not United States real property interests as defined in Section 897(c)(1) of the Code, (ii) file such certification with the Internal Revenue Services in the manner and within the time period specified in Treasury regulations Section 1.897-2(h) and (iii) promptly after such filing, furnish to Jefferies & Company, Inc. or the Underwriter that has requested a certificate, as the case may be, proof of such filing.

## 5. COSTS AND EXPENSES.

The Company will pay all costs, expenses and fees incident to the performance of the obligations of the Company under this Agreement except as expressly stated in this Agreement, including, without limiting the generality of the foregoing, the following: accounting fees of the Company; the fees and disbursements of counsel for the Company; the cost of printing and delivering to, or as requested by, the Underwriters copies of the Registration Statement, Preliminary Prospectuses, the Issuer Free Writing Prospectuses, the Prospectus, this Agreement, the Underwriters' Invitation Letter, and the Listing Application; the filing fees of the Commission; the filing fees and expenses (including reasonable legal fees and disbursements) incident to securing any required review by the NASD of the terms of the sale of the Shares; the Listing Fee of the Nasdaq National Market; the costs and expenses (including without limitation any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Shares made by the Underwriters caused by a breach of the representation in Section 1(b); and the expenses, including the reasonable fees and disbursements of counsel for the Underwriters, incurred in connection with the qualification of the Shares under State securities or Blue Sky laws. The Company shall not, however, be required to pay for any of the Underwriter's expenses (other than those related to qualification under NASD regulation and State securities or Blue Sky laws) except that, if this Agreement shall not be consummated because the conditions in Section 6 hereof are not satisfied, or because this Agreement is terminated by the Representatives pursuant to Section 11 hereof, or by reason of any failure, refusal or inability on the part of the Company to perform any undertaking or satisfy any condition of this Agreement or to comply with any of the terms hereof on its part to be performed, unless

such failure, refusal or inability results from a termination of this Agreement in accordance with clause (b) of the second sentence of Section 9 hereof, the Company shall reimburse the several Underwriters for reasonable out-of-pocket expenses, including fees and disbursements of counsel, reasonably incurred in connection with investigating, marketing and proposing to market the Shares or in contemplation of performing their obligations hereunder; but the Company shall not in any event be liable to any of the several Underwriters for damages on account of loss of anticipated profits from the sale by them of the Shares.

6. CONDITIONS OF OBLIGATIONS OF THE UNDERWRITERS.

The several obligations of the Underwriters to purchase the Firm Shares on the Closing Date and the Option Shares, if any, on the Option Closing Date are subject to the accuracy, as of the Applicable Time, the Closing Date or the Option Closing Date, as the case may be, of the representations and warranties of the Company contained herein, and to the performance by the Company of its covenants and obligations hereunder and to the following additional conditions:

16

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(a) The Registration Statement and all post-effective amendments thereto shall have become effective and the Prospectus and each Issuer Free Writing Prospectus required shall have been filed as required by Rules 424, 430A, 430B, 430C or 433 under the Act, as applicable, within the time period prescribed by, and in compliance with, the Rules and Regulations, and any request of the Commission for additional information (to be included in the Registration Statement or otherwise) shall have been disclosed to the Representatives and complied with to its reasonable satisfaction. No stop order suspending the effectiveness of the Registration Statement, as amended from time to time, shall have been issued and no proceedings for that purpose or pursuant to Section 8A under the Act shall have been taken or, to the knowledge of the Company, shall be contemplated or threatened by the Commission and no injunction, restraining order or order of any nature by a Federal or state court of competent jurisdiction shall have been issued as of the Closing Date or the Option Closing Date, as applicable, which would prevent the issuance of the Shares.

(b) The Representatives shall have received on the Closing Date or the Option Closing Date, as the case may be, the opinion of Ballard Spahr Andrews & Ingersoll, LLP, counsel for the Company, dated the Closing Date or the Option Closing Date, as the case may be, addressed to the Underwriters to the effect that:

(i) The Company is validly existing as a corporation in good standing under the laws of the State of Delaware, with corporate power and authority to own or lease its properties and conduct its business as described in the Registration Statement; and the Company is duly qualified to transact business in the State of Maryland.

(ii) The Company has authorized and outstanding capital stock as set forth under the caption "Capitalization" in the Registration Statement and the Prospectus (and any similar section or information contained in the General Disclosure Package); the authorized shares of the Company's Common Stock have been duly authorized; the outstanding shares of the Company's Common Stock have been duly authorized and validly issued and are fully paid and non-assessable; all of the Shares conform to the description thereof contained in the Registration Statement, the General Disclosure Package and the Prospectus; the certificates for the Shares, assuming they are in the form filed with the Commission, are in due and proper form; the shares of Common Stock, including the Option Shares, if any, to be sold by the Company pursuant to this Agreement have been duly authorized and will be validly issued, fully paid and non-assessable when issued and paid for as contemplated by this Agreement; and except as described in the Registration Statement, the General Disclosure Package and the Prospectus, no preemptive rights of stockholders exist with respect to any of the Shares or the issue or sale thereof.

(iii) Except as described in or contemplated by the Registration Statement, the General Disclosure Package and the Prospectus, to such counsel's knowledge, there are no outstanding securities of the Company convertible or exchangeable into or evidencing the right to purchase or subscribe for any shares of capital stock of the Company and there are no outstanding or authorized options, warrants or rights of any character obligating the Company to issue any shares of its capital stock or any securities convertible or exchangeable into or evidencing the right to purchase or subscribe for any shares of such stock; and except as described in the Registration Statement, the General Disclosure Package

and the Prospectus, no holder of any securities of the Company or any other person has the right, contractual or otherwise, which has not been satisfied or

effectively waived, to cause the Company to sell or otherwise issue to them, or to permit them to underwrite the sale of, any of the Shares or the right to have any Common Shares or other securities of the Company included in the Registration Statement or the right, as a result of the filing of the Registration Statement, to require registration under the Act of any shares of Common Stock or other securities of the Company.

(iv) Such counsel has been informed by the staff of the Commission that the Registration Statement has become effective under the Act and that no stop order proceedings with respect thereto and no proceeding for that purpose or pursuant to Section 8A of the Act have been instituted or are pending or threatened under the Act.

(v) The Registration Statement, the Prospectus and each amendment or supplement thereto comply as to form in all material respects with the requirements of the Act and the applicable rules and regulations thereunder (except that such counsel need express no opinion as to the financial statements and related schedules therein).

(vi) The statements under the captions “Risk Factors – Certain provisions of Delaware law and of our charter documents contain provisions that could delay and discourage takeover attempts and any attempts to replace our current management by stockholders,” “Business – Collaborations,” “Management – Composition of our Board of Directors,” “– Committees of the Board of Directors,” “– Employment Agreements” and “– Employee Benefits Plans,” “Certain Relationships and Related Party Transactions,” “Description of Capital Stock” and “Shares Eligible for Future Sale,” in the Prospectus and under the captions “Item 14. Indemnification of Directors and Officers” and “Item 15. Recent Sales of Unregistered Securities” in Part II of the Registration Statement, insofar as such statements constitute a summary of documents referred to therein or matters of law, fairly summarize in all material respects the information purported to be stated therein.

(vii) Such counsel does not know of any contracts or documents required to be filed as exhibits to the Registration Statement or described in the Registration Statement or the Prospectus which are not so filed or described as required, and such contracts and documents as are summarized in the Registration Statement or the Prospectus are fairly summarized in all material respects.

(viii) Such counsel knows of no material legal or governmental proceedings pending or threatened against the Company or the Subsidiary except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus.

(ix) The execution and delivery of this Agreement and the consummation of the transactions contemplated herein do not and will not conflict with or violate any of the terms or provisions of the certificate of incorporation or by-laws of the Company, each as amended to date, or conflict with or result in a breach of, or default under, any of the terms or provisions of any material indenture, mortgage, deed of trust or other agreement or instrument to which the Company is a party or by which the Company may be bound that is filed as an exhibit to the Registration Statement.

(x) This Agreement has been duly authorized, executed and delivered by the Company.

(xi) No approval, consent, order, authorization, designation, declaration or filing by or with any regulatory, administrative or other governmental body is necessary in connection with the execution and delivery of this Agreement and the consummation of

the transactions herein contemplated (other than as may be required by the NASD or as required by State securities and Blue Sky laws as to which such counsel need express no opinion) except such as have been obtained or made.

(xii) The Company is not, and will not become, as a result of the consummation of the transactions contemplated by this Agreement, and application of the net proceeds therefrom as described in the Prospectus, required to register as an investment company under the 1940 Act.

(xiii) Any required filing of each Issuer Free Writing Prospectus pursuant to Rule 433 under the Act has been made within the time period required by Rule 433(d) under the Act.

(xiv) The statements set forth in the Prospectus under the caption “Material United States Federal Income and Estate Tax Consequences to Non-United States Holders” constitute an accurate and complete summary of the matters discussed therein in all material respects and, as to such matters, fairly presents all material United States tax consequences to a purchaser of the Shares that is a “non-U.S. Holder” (as defined in the Prospectus).

In rendering such opinion Ballard Spahr Andrews & Ingersoll, LLP may rely as to matters governed by the laws of states other than Delaware or Federal laws on local counsel in such jurisdictions, provided that in each case Ballard Spahr Andrews & Ingersoll, LLP shall state that they believe that they and the Underwriters are justified in relying on such other counsel.

In addition to the matters set forth above, such opinion shall also include a statement to the effect that nothing has come to the attention of such counsel which leads them to believe that (i) the Registration Statement, at the time it became effective under the Act (including the information deemed to be a part of the Registration Statement at the time it became effective pursuant to Rules 430A, 430B or 430C under the Act) and as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the General Disclosure Package, as of the Applicable Time, contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (iii) the Prospectus, or any supplement thereto, on the date it was filed pursuant to the Rules and Regulations and as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (except that such counsel need express no view as to

financial statements and schedules thereto and other financial and statistical data derived therefrom). With respect to such statement, Ballard Spahr Andrews & Ingersoll, LLP may state that their belief is based upon the procedures set forth therein, but is without independent check and verification. Such opinion shall also include a statement to the effect that the opinion is not intended or written by counsel to be used, and such advice cannot be used by any recipient, for the purpose of avoiding penalties that may be imposed by any taxing authority and that any legal advice was written to support the promotion and marketing of the Shares and each taxpayer receiving this opinion should seek advice based on such taxpayer’s particular circumstances from an independent tax advisor.

(c) The Representatives shall have received on the Closing Date or the Option Closing Date, as the case may be, the opinion of Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, special intellectual property counsel for the Company, dated the Closing Date or the Option Closing Date, as the case may be, addressed to the Underwriters (and stating that it may be relied upon by counsel to the Underwriters) to the effect that:

(i) The statements under the captions “Risk Factors – Risks Related to Intellectual Property” and “Business – Intellectual Property,” in the Registration Statement and the Prospectus, at the time the Registration Statement became effective, as of the Applicable Time, on the Closing Date and on any Option Closing Date, insofar as such statements constitute a summary of patents, patent

applications, agreements or other documents referred to therein or matters of law, are accurate in all material respect and fairly summarize the information purported to be described.

(ii) To such counsel' s knowledge, the Company owns the United States patents and United States patent applications listed in the schedule attached to its opinion and any foreign counterparts thereof. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, to such counsel' s knowledge there is no pending or threatened action, suit or proceeding or asserted claim by others challenging the Company' s ownership to such patents or patent applications, or the validity or enforceability of any granted patents owned by or licensed to the Company.

(iii) To such counsel' s knowledge, there is no pending or threatened action, suit or proceeding or asserted claim by governmental authorities or others that the Company is infringing or otherwise violating, or would upon commercialization and sale of the product, candidates of the Company described in the Registration Statement and the Prospectus infringe or otherwise violate, any patent, trademark, copyright or trade secret rights of others, and, to our knowledge, and other than disclosed in the Prospectus, the Company is not infringing or otherwise violating, and upon the commercialization and sale of the product candidates of the Company described in the Registration Statement and the Prospectus, would not infringe or otherwise violate rights of others.

(iv) To such counsel' s knowledge, other than as disclosed in the Prospectus, there are no infringements by others of any of the patents and pending patent applications that the Company owns or has a right to enforce.

In rendering such opinion Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein may rely as to matters governed by the laws of states other than Delaware or Federal laws

on local counsel in such jurisdictions, provided that in each case Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein shall state that they believe that they and the Underwriters are justified in relying on such other counsel.

In addition to the matters set forth above, such opinion shall also include a statement to the effect that nothing has come to the attention of such counsel which leads them to believe that, insofar as the Intellectual Property disclosures are concerned (i) the Registration Statement, at the time it became effective under the Act (including the information deemed to be a part of the Registration Statement at the time it became effective pursuant to Rules 430A, 430B or 430C under the Act) and as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the General Disclosure Package, as of the Applicable Time, contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (iii) the Prospectus, or any supplement thereto, on the date it was filed pursuant to the Rules and Regulations and as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (except that such counsel need express no view as to financial statements and schedules and other financial data therein). With respect to such statement, Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein may state that their belief is based upon the procedures set forth therein, but is without independent check and verification.

(d) The Representatives shall have received on the Closing Date or the Option Closing Date, as the case may be, the opinion of Morgan, Lewis & Bockius LLP, special regulatory counsel for the Company, dated the Closing Date or the Option Closing Date, as the case may be, addressed to the Underwriters (and stating that it may be relied upon by counsel to the Underwriters) to the effect that:

(i) The statements in Registration Statement and the Prospectus (and any similar section or information contained in the General Disclosure Package) and any amendment or supplement thereto made available and reviewed by such counsel under the captions “Risk Factors – Risks Related to Regulatory Approval and Other Governmental Regulations” (excluding the subcaption “Our business involves the use of hazardous materials that could expose us to environmental and other liability”) and “Business – Government Regulation” regarding (a) healthcare regulatory matters or (b) the receipt by the Company of governmental approvals or clearances, and the applications for, or the submissions with the Food and Drug Administration regarding, such approvals or clearances (collectively, the “Regulatory Statements”), insofar as such Regulatory Statements constitute summaries of documents or legal proceedings or refer to matters of law or legal conclusions, were, at the time the Registration Statement became effective and as of the Applicable Time, and are, on the Closing Date and any Option Closing Date, accurate in all material respects and presented and present fairly the information purported to be described herein.

In rendering such opinion Morgan, Lewis & Bockius LLP may rely as to matters governed by the laws of states other than Delaware or Federal laws on local counsel in such jurisdictions, provided that in each case Morgan, Lewis & Bockius LLP shall state that they believe that they and the Underwriters are justified in relying on such other counsel.

(e) The Representatives shall have received from Dewey Ballantine LLP, counsel for the Underwriters, an opinion dated the Closing Date or the Option Closing Date, as the case may be, substantially to the effect specified in subparagraphs (ii), (iii), (iv) and (x) of Paragraph (b) of this Section 6, and that the Company is a duly organized and validly existing corporation under the laws of the State of Delaware. In rendering such opinion Dewey Ballantine LLP may rely as to all matters governed other than by the laws of the State of New York or Federal laws on the opinion of counsel referred to in Paragraph (b) of this Section 6. In addition to the matters set forth above, such opinion shall also include a statement to the effect that nothing has come to the attention of such counsel which leads them to believe that (i) the Registration Statement, or any amendment thereto, as of the time it became effective under the Act (including the information deemed to be a part of the Registration Statement at the time it became effective pursuant to Rules 430A, 430B or 430C under the Act) as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the General Disclosure Package, as of the Applicable Time, contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (iii) the Prospectus, or any supplement thereto, on the date it was filed pursuant to the Rules and Regulations and as of the Closing Date or the Option Closing Date, as the case may be, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact, necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (except that such counsel need express no view as to financial statements and schedules and other financial data therein). With respect to such statement, Dewey Ballantine LLP may state that their belief is based upon the procedures set forth therein, but is without independent check and verification.

(f) You shall have received, on each of the date hereof, the Closing Date and, if applicable, the Option Closing Date, a letter dated the date hereof, the Closing Date or the Option Closing Date, as the case may be, in form and substance satisfactory to you, of Stegman & Company PC confirming that they are an independent registered public accounting firm with respect to the Company and the Subsidiary within the meaning of the Act and the applicable Rules and Regulations and the PCAOB and stating that in their opinion the financial statements and schedules examined by them and included in the Registration Statement, the General Disclosure Package and the Prospectus comply in form in all material respects with the applicable accounting requirements of the Act and the related Rules and Regulations; and containing such other statements and information as is ordinarily included in accountants’ “comfort letters” to underwriters with respect to the financial statements and certain financial and statistical information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(g) The Representatives shall have received on the Closing Date and, if applicable, the Option Closing Date, as the case may be, a certificate or certificates of the Chief Executive

Officer and the Chief Financial Officer of the Company to the effect that, as of the Closing Date or the Option Closing Date, as the case may be, each of them severally represents as follows:

(i) The Registration Statement has become effective under the Act and no stop order suspending the effectiveness of the Registration Statement or no order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus has been issued, and no proceedings for such purpose or pursuant to Section 8A of the Act have been taken or are, to his or her knowledge, contemplated or threatened by the Commission;

(ii) The representations and warranties of the Company contained in Section 1 hereof are true and correct as of the Closing Date or the Option Closing Date, as the case may be;

(iii) All filings required to have been made pursuant to Rules 424, 430A, 430B or 430C under the Act have been made as and when required by such rules;

(iv) He or she has carefully examined the General Disclosure Package and any individual Limited Use Free Writing Prospectus and, in his or her opinion, as of the Applicable Time, the statements contained in the General Disclosure Package and any individual Limited Use Free Writing Prospectus did not contain any untrue statement of a material fact, and such General Disclosure Package and any individual Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package, did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(v) He or she has carefully examined the Registration Statement and, in his or her opinion, as of the effective date of the Registration Statement, the Registration Statement and any amendments thereto did not contain any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein not misleading, and since the effective date of the Registration Statement, no event has occurred which should have been set forth in a supplement to or an amendment of the Prospectus which has not been so set forth in such supplement or amendment;

(vi) He or she has carefully examined the Prospectus and, in his or her opinion, as of its date and the Closing Date or the Option Closing Date, as the case may be, the Prospectus and any amendments and supplements thereto did not contain any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and

(vii) Since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package and Prospectus, there has not been any material adverse change or any development involving a prospective material adverse change in or affecting the business, management, properties, assets, rights, operations, condition (financial or otherwise) or prospects of the Company and the Subsidiary taken as a whole, whether or not arising in the ordinary course of business.

(h) The Company shall have furnished to the Representatives such further certificates and documents confirming the representations and warranties, covenants and conditions contained herein and related matters as the Representatives may reasonably have requested.

(i) The Firm Shares and Option Shares, if any, shall have been approved for quotation upon notice of issuance on the Nasdaq National Market.

(j) The Lockup Agreements described in Section 4(l) are in full force and effect.

The opinions and certificates mentioned in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in all material respects satisfactory to the Representatives and to Dewey Ballantine LLP, counsel for the Underwriters.

If any of the conditions hereinabove provided for in this Section 6 shall not have been fulfilled when and as required by this Agreement to be fulfilled, the obligations of the Underwriters hereunder may be terminated by the Representatives by notifying the Company of such termination in writing or by telegram at or prior to the Closing Date or the Option Closing Date, as the case may be.

In such event, the Company and the Underwriters shall not be under any obligation to each other (except to the extent provided in Sections 5 and 8 hereof).

7. CONDITIONS OF THE OBLIGATIONS OF THE COMPANY.

The obligations of the Company to sell and deliver the portion of the Shares required to be delivered as and when specified in this Agreement are subject to the conditions that at the Closing Date or the Option Closing Date, as the case may be, no stop order suspending the effectiveness of the Registration Statement shall have been issued and in effect or proceedings therefor initiated or threatened.

8. INDEMNIFICATION.

(a) The Company agrees:

(i) to indemnify and hold harmless each Underwriter and each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Act or Section 20 of the Exchange Act, against any losses, claims, damages or liabilities to which such Underwriter or any such controlling person may become subject under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of or are based upon (A) any untrue statement or alleged untrue statement of any material fact contained in the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus the Prospectus or any amendment or supplement thereto or (B) the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances under which they were made; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises

out of or is based upon an untrue statement or alleged untrue statement, or omission or alleged omission made in the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus, or such amendment or supplement, in reliance upon and in conformity with written information furnished to the Company by or through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 13 herein; and

(ii) to reimburse each Underwriter and each such controlling person upon demand for any legal or other out-of-pocket expenses reasonably incurred by such Underwriter or such controlling person in connection with investigating or defending any such loss, claim, damage or liability, action or proceeding, whether or not such Underwriter or controlling person is a party to any action or proceeding. In the event that it is finally judicially determined that the Underwriters were not entitled to receive payments for legal and other expenses pursuant to this subparagraph, the Underwriters will promptly return all sums that had been advanced pursuant hereto.

(b) Each Underwriter severally and not jointly will indemnify and hold harmless the Company, each of its directors, each of its officers who have signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Act, against any



losses, claims, damages or liabilities to which the Company or any such director, officer, or controlling person may become subject under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of or are based upon (i) any untrue statement or alleged untrue statement of any material fact contained in the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus or any amendment or supplement thereto, or (ii) the omission or the alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances under which they were made; and will reimburse any legal or other expenses reasonably incurred by the Company or any such director, officer, or controlling person in connection with investigating or defending any such loss, claim, damage, liability, action or proceeding; provided, however, that each Underwriter will be liable in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission has been made in the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus or such amendment or supplement, in reliance upon and in conformity with written information furnished to the Company by or through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 13 herein. This indemnity agreement will be in addition to any liability which such Underwriter may otherwise have.

(c) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to this Section 8, such person (the “indemnified party”) shall promptly notify the person against whom such indemnity may be sought (the “indemnifying party”) in writing. No indemnification provided for in Section 8(a) or (b) shall be available to any party who shall fail to give notice as provided in this Section 8(d) if the party to whom notice was not given was unaware of the proceeding to which

such notice would have related and was materially prejudiced by the failure to give such notice, but the failure to give such notice shall not relieve the indemnifying party or parties from any liability which it or they may have to the indemnified party for contribution or otherwise than on account of the provisions of Section 8(a) or (b). In case any such proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party and shall pay as incurred the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel at its own expense. Notwithstanding the foregoing, the indemnifying party shall pay as incurred (or within 30 days of presentation) the fees and expenses of the counsel retained by the indemnified party in the event (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them or (iii) the indemnifying party shall have failed to assume the defense and employ counsel acceptable to the indemnified party within a reasonable period of time after notice of commencement of the action. It is understood that the indemnifying party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate firm for all such indemnified parties. Such firm shall be designated in writing by you in the case of parties indemnified pursuant to Section 8(a) and by the Company in the case of parties indemnified pursuant to Section 8(b). The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. In addition, the indemnifying party will not, without the prior written consent of the indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding of which indemnification may be sought hereunder (whether or not any indemnified party is an actual or potential party to such claim, action or proceeding) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action or proceeding.

(d) To the extent the indemnification provided for in this Section 8 is unavailable to or insufficient to hold harmless an indemnified party under Section 8(a) or (b) above in respect of any losses, claims, damages or liabilities (or actions or proceedings in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) in such proportion as is appropriate to reflect the relative

benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Shares. If, however, the allocation provided by the immediately preceding sentence is not permitted by applicable law then each indemnifying party shall contribute to such amount paid or payable by such indemnified party in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities (or actions or proceedings in respect thereof), as well as any other relevant equitable

considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or the Underwriters on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company, and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 8(d) were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 8(d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions or proceedings in respect thereof) referred to above in this Section 8(d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), (i) no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Shares purchased by such Underwriter and (ii) no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations in this Section 8(d) to contribute are several in proportion to their respective underwriting obligations and not joint.

(e) In any proceeding relating to the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus or any supplement or amendment thereto, each party against whom contribution may be sought under this Section 8 hereby consents to the jurisdiction of any court having jurisdiction over any other contributing party, agrees that process issuing from such court may be served upon it by any other contributing party and consents to the service of such process and agrees that any other contributing party may join it as an additional defendant in any such proceeding in which such other contributing party is a party.

(f) Any losses, claims, damages, liabilities or expenses for which an indemnified party is entitled to indemnification or contribution under this Section 8 shall be paid by the indemnifying party to the indemnified party as such losses, claims, damages, liabilities or expenses are incurred. The indemnity and contribution agreements contained in this Section 8 and the representations and warranties of the Company set forth in this Agreement shall remain operative and in full force and effect, regardless of (i) any investigation made by or on behalf of any Underwriter or any person controlling any Underwriter, the Company, its directors or officers or any persons controlling the Company, (ii) acceptance of any Shares and payment therefor hereunder, and (iii) any termination of this Agreement. A successor to any Underwriter, or any person controlling any Underwriter, or to the Company, its directors or officers, or any person controlling the Company, shall be entitled to the benefits of the indemnity, contribution and reimbursement agreements contained in this Section 8.

9. DEFAULT BY UNDERWRITERS.

If on the Closing Date or the Option Closing Date, as the case may be, any Underwriter shall fail to purchase and pay for the portion of the Shares which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), you, as Representatives of the Underwriters, shall use your reasonable efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Shares which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours you, as such Representatives, shall not have procured such other Underwriters, or any others, to purchase the Shares agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of shares with respect to which such default shall occur does not exceed 10% of the Shares to be purchased on the Closing Date or the Option Closing date, as the case may be, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Shares which they are obligated to purchase hereunder, to purchase the Shares which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of shares of Shares with respect to which such default shall occur exceeds 10% of the Shares to be purchased on the Closing Date or the Option Closing Date, as the case may be, the Company or you as the Representatives of the Underwriters will have the right, by written notice given within the next 36-hour period to the parties to this Agreement, to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except as set forth in Section 8 hereof and in the first sentence of Section 5 hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Section 9, the Closing Date or Option Closing Date, as the case may be, may be postponed for such period, not exceeding seven days, as you, as Representatives, may determine in order that the required changes in the Registration Statement, the General Disclosure Package or in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any person substituted for a defaulting Underwriter. Any action taken under this Section 9 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

10. NOTICES.

All communications hereunder shall be in writing and, except as otherwise provided herein, will be mailed, delivered, telecopied or telegraphed and confirmed as follows: if to the Underwriters, to Jefferies & Company, Inc., 520 Madison Avenue, New York, New York 10022; Attention: [Syndicate Manager], with a copy to Jefferies & Company, Inc., 520 Madison Avenue, New York, New York 10022, Attention: [General Counsel]; if to the Company, to Osiris Therapeutics, Inc., 2001 Aliceanna Street, Baltimore, Maryland 21231, Attention: C. Randal Mills, Ph.D., President and Chief Executive Officer.

11. TERMINATION.

This Agreement may be terminated by you by notice to the Company (a) at any time prior to the Closing Date or any Option Closing Date (if different from the Closing Date and then only as to Option Shares) if any of the following has occurred: (i) since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package and the

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Prospectus, any material adverse change or any development involving a prospective material adverse change in or affecting the earnings, business, management, properties, assets, rights, operations, condition (financial or otherwise) or prospects of the Company and the Subsidiary taken as a whole, whether or not arising in the ordinary course of business, (ii) any outbreak or escalation of hostilities or declaration of war or national emergency or other national or international calamity or crisis or change in economic or political conditions if the effect of such outbreak, escalation, declaration, emergency, calamity, crisis or change on the financial markets of the United States would, in your judgment, make it impracticable or inadvisable to market the Shares or to enforce contracts for the sale of the Shares, or (iii) suspension of trading in securities generally on the New York Stock Exchange, the American Stock Exchange or the Nasdaq National Market or limitation on prices (other than limitations on hours or numbers of days of trading) for securities on either such Exchange, (iv) the enactment, publication, decree or other promulgation of any statute, regulation, rule or order of any court or other governmental authority which in your opinion materially and adversely affects or may materially and adversely affect the business or operations of the Company, (v) the declaration of a banking moratorium by United States or New York State authorities, (vi) any downgrading, or placement on any watch list for possible downgrading, in the rating of any of the

Company's debt securities by any "nationally recognized statistical rating organization" (as defined for purposes of Rule 436(g) under the Exchange Act); (vii) the suspension of trading of the Company's common stock by the Nasdaq National Market, the Commission, or any other governmental authority or, (viii) the taking of any action by any governmental body or agency in respect of its monetary or fiscal affairs which in your reasonable opinion has a material adverse effect on the securities markets in the United States; or

(b) as provided in Sections 6 and 9 of this Agreement.

12. SUCCESSORS.

This Agreement has been and is made solely for the benefit of the Underwriters and the Company and their respective successors, executors, administrators, heirs and assigns, and the officers, directors and controlling persons referred to herein, and no other person will have any right or obligation hereunder. No purchaser of any of the Shares from any Underwriter shall be deemed a successor or assign merely because of such purchase.

13. INFORMATION PROVIDED BY UNDERWRITERS.

The Company and the Underwriters acknowledge and agree that the only information furnished or to be furnished by any Underwriter to the Company for inclusion in the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus consists of the information set forth in the [third, ninth, and tenth through fifteenth] paragraphs under the caption "Underwriting" in the Prospectus.

14. NO ADVISORY OR FIDUCIARY RELATIONSHIP.

The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length

commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

15. RESEARCH ANALYST INDEPENDENCE.

The Company acknowledges that the Underwriters' research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such Underwriters' research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that each of the Underwriters is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

16. MISCELLANEOUS.

The reimbursement, indemnification and contribution agreements contained in this Agreement and the representations, warranties and covenants in this Agreement shall remain in full force and effect regardless of (a) any termination of this Agreement, (b) any investigation made by or on behalf of any Underwriter or controlling person thereof, or by or on behalf of the Company or its directors or officers, and (c) delivery of and payment for the Shares under this Agreement.

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

This Agreement shall be governed by, and construed in accordance with, the law of the State of New York, including, without limitation, Section 5-1401 of the New York General Obligations Law.

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If the foregoing letter is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicates hereof, whereupon it will become a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

Osiris Therapeutics, Inc.

By \_\_\_\_\_

The foregoing Underwriting Agreement  
is hereby confirmed and accepted as  
of the date first above written.

JEFFERIES & COMPANY, INC.

As Representatives of the several  
Underwriters listed on Schedule I

By: Jefferies & Company, Inc.

By \_\_\_\_\_  
Authorized Officer

By \_\_\_\_\_  
Authorized Officer

31

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SCHEDULE I

SCHEDULE OF UNDERWRITERS

Underwriter

Number of Firm Shares  
to be Purchased

Jefferies & Company, Inc.  
Lazard Capital Markets LLC  
Leerink Swann & Co.

Total

\_\_\_\_\_  
\_\_\_\_\_

32

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SCHEDULE II

None.

33

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SCHEDULE III

None.

## EXHIBIT A

LOCK-UP AGREEMENT

[Date]

Osiris Therapeutics, Inc.

Deutsche Bank Securities Inc.

As Representatives of the  
Several Underwritersc/o Deutsche Bank Securities Inc.  
60 Wall Street, 4<sup>th</sup> Floor  
New York, New York 10005

Ladies and Gentlemen:

The undersigned understands that Deutsche Bank Securities Inc., as Representatives (“DBSI”) of the several underwriters (the “Underwriters”), propose to enter into an Underwriting Agreement (the “Underwriting Agreement”) with Osiris Therapeutics, Inc. (the “Company”), providing for the public offering by the Underwriters, including DBSI, of common stock, par value \$0.001 (the “Common Stock”), of the Company (the “Public Offering”).

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned agrees that, without the prior written consent of DBSI, the undersigned will not, directly or indirectly, offer, sell, pledge, contract to sell (including any short sale), grant any option to purchase or otherwise dispose of any shares of Common Stock (including, without limitation, shares of Common Stock of the Company which may be deemed to be beneficially owned by the undersigned on the date hereof in accordance with the rules and regulations of the Securities and Exchange Commission, shares of Common Stock which may be issued upon exercise of a stock option or warrant and any other security convertible into or exchangeable for Common Stock) or enter into any Hedging Transaction (as defined below) relating to the Common Stock (each of the foregoing referred to as a “Disposition”) during the period specified in the following paragraph (the “Lock-Up Period”). The foregoing restriction is expressly intended to preclude the undersigned from engaging in any Hedging Transaction or other transaction which is designed to or reasonably expected to lead to or result in a Disposition during the Lock-Up Period even if the securities would be disposed of by someone other than the undersigned. “Hedging Transaction” means any short sale (whether or not against the box) or any purchase, sale or grant of any right (including, without limitation, any put or call option) with

respect to any security (other than a broad-based market basket or index) that includes, relates to or derives any significant part of its value from the Common Stock.

The initial Lock-Up Period will commence on the date hereof and continue until, and include, the date that is 180 days after the date of the final prospectus relating to the Public Offering (the "Initial Lock-Up Period"); provided, however, that if (1) during the last 17 days of the Initial Lock-Up Period, (A) the Company releases earnings results or (B) material news or a material event relating to the Company occurs, or (2) prior to the expiration of the Initial Lock-Up Period, the Company announces that it will release earnings results during the 16-day period following the last day of the Initial Lock-Up Period, then in each case the Lock-Up Period will be extended until the expiration of the 18-day period beginning on the date of the release of the earnings results or the occurrence of material news or a material event relating to the Company, as the case may be, unless DBSI waives, in writing, such extension.

Notwithstanding the foregoing, the undersigned may transfer (a) shares of Common Stock acquired in open market transactions by the undersigned after the completion of the Public Offering, and (b) any or all of the shares of Common Stock or other Company securities if the transfer is by (i) gift, will or intestacy, or (ii) distribution to partners, members or shareholders of the undersigned; provided, however, that in the case of a transfer pursuant to clause (b) above, it shall be a condition to the transfer that the transferee execute an agreement stating that the transferee is receiving and holding the securities subject to the provisions of this Lock-Up Agreement.

The undersigned agrees that the Company may, and that the undersigned will, (i) with respect to any shares of Common Stock or other Company securities for which the undersigned is the record holder, cause the transfer agent for the Company to note stop transfer instructions with respect to such securities on the transfer books and records of the Company and (ii) with respect to any shares of Common Stock or other Company securities for which the undersigned is the beneficial holder but not the record holder, cause the record holder of such securities to cause the transfer agent for the Company to note stop transfer instructions with respect to such securities on the transfer books and records of the Company.

In addition, the undersigned hereby waives any and all notice requirements and rights with respect to registration of securities pursuant to any agreement, understanding or otherwise setting forth the terms of any security of the Company held by the undersigned, including any registration rights agreement to which the undersigned and the Company may be party; provided that such waiver shall apply only to the proposed Public Offering, and any other action taken by the Company in connection with the proposed Public Offering.

The undersigned hereby agrees that, to the extent that the terms of this Lock-Up Agreement conflict with or are in any way inconsistent with any registration rights agreement to which the undersigned and the Company may be a party, this Lock-Up Agreement supersedes such registration rights agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Lock-Up Agreement. All authority herein conferred or agreed to be conferred shall survive the death or incapacity of the undersigned and any obligations of the

undersigned shall be binding upon the heirs, personal Representatives, successors and assigns of the undersigned.

Notwithstanding anything herein to the contrary, if the closing of the Public Offering has not occurred prior to December 31, 2006, this agreement shall be of no further force or effect.

*Signature:* \_\_\_\_\_

*Print Name:* \_\_\_\_\_

Number of shares owned  
subject to warrants, options  
or convertible securities:

Certificate numbers:



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