HYBRIDON INC
Form 8-K
April 15, 2004

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): April 15, 2004

HYBRIDON, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	001-31918	04-3072298
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identifi

345 Vassar Street, Cambridge, Massachusetts	02139
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 679-5500

Not Applicable

(Former Name or Former Address if Changed Since Last Report)

ITEM 5. OTHER EVENTS AND REQUIRED FD DISCLOSURE

On January 30, 2004, the Securities and Exchange Commission declared effective the Registration Statement on Form S-3 (File No. 333-111903) (the "Registration Statement") of Hybridon, Inc. (the "Company"). The Registration Statement permits the Company to issue, in one or more offerings, shares of common stock and warrants to purchase shares of common stock. The total number

of shares of common stock that the Company may issue in such offerings or upon exercise of warrants issued in such offerings may not exceed 20,000,000.

On April 15, 2004, the Company entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Thomas Weisel Partners LLC, Rodman & Renshaw and Merriman Curhan Ford & Co. (the "Placement Agents"). Pursuant to the Placement Agency Agreement, the Placement Agents have agreed to act as the Company's placement agents in connection with an offering of units, each unit consisting of 100 shares of the Company's common stock and warrants to purchase 18 shares of the Company's common stock at an exercise price of $1.14 per share (the "Offering"), under the Registration Statement.

In connection with the Placement Agency Agreement and the Offering, the Company is filing as exhibits to this Current Report on Form 8-K the following documents:

- as Exhibit 1.1, the Placement Agency Agreement, including as Exhibit B thereto the form of Purchase Agreement to be entered into by the Company and the investors;
- as Exhibit 4.1, the form of Warrant to be issued to investors in the Offering; and
- as Exhibits 5.1 and 23.1, the legal opinion of Hale and Dorr LLP relating to the shares of common stock and warrants to be issued and sold in the Offering.

This Current Report on Form 8-K does not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company and these securities cannot be sold in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state.

In addition, the Company is providing below, under the caption "Risk Factors," an updated description of the risks and uncertainties that could materially affect the Company's business, financial condition and results of operations.

RISK FACTORS

The following important factors could cause actual results to differ from those indicated by forward-looking statements made by us in this current report on Form 8-K and elsewhere from time to time.

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

WE HAVE INCURRED SUBSTANTIAL LOSSES AND EXPECT TO CONTINUE TO INCUR LOSSES. WE WILL NOT BE SUCCESSFUL UNLESS WE REVERSE THIS TREND.

We have incurred losses in every year since our inception, except for 2002 when our recognition of revenues under a license and collaboration agreement resulted in us reporting net income for that year. As of December 31, 2003, we had incurred operating losses of approximately $283.9 million. We expect to continue to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

We have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaborative and license agreements and the sale of manufactured synthetic DNA and reagent products by our Hybridon

Specialty Products Division prior to our selling that division in September 2000. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available, or when we will become profitable, if at all.

WE WILL NEED ADDITIONAL FINANCING, WHICH MAY BE DIFFICULT TO OBTAIN. OUR FAILURE TO OBTAIN NECESSARY FINANCING OR DOING SO ON UNATTRACTIVE TERMS COULD ADVERSELY AFFECT OUR DISCOVERY AND DEVELOPMENT PROGRAMS AND OTHER OPERATIONS.

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drugs. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing and sales capabilities. We believe that, based on our current operating plan, our existing cash and cash equivalents and short term investments will be sufficient to fund our cash requirements through the end of December 2004, or, if the offering contemplated by the placement agency agreement attached to this current report on Form 8-K is consummated, to fund our cash requirements through mid-2005. We will need to raise additional funds to operate our business beyond such time.

Additional financing may not be available to us when we need it or may not be available to us on favorable terms. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to significantly curtail one or more of our discovery or development programs. For example, we significantly curtailed expenditures on our research and development programs during 1999 and 2000 because we did not have sufficient funds available to advance these programs at planned levels. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, drug candidates or drugs which we would otherwise pursue on our own.

If we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. In addition, the terms of the financing may adversely affect the holdings or the rights of existing stockholders.

OUR FORMER INDEPENDENT PUBLIC ACCOUNTANT, ARTHUR ANDERSEN LLP, HAS BEEN FOUND GUILTY OF A FEDERAL OBSTRUCTION OF JUSTICE CHARGE. ARTHUR ANDERSEN LLP HAS NOT CONSENTED TO THE INCLUSION OF ITS AUDIT REPORT WITH RESPECT TO OUR CONSOLIDATED FINANCIAL STATEMENTS IN OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2003, AND YOU MAY BE UNABLE TO EXERCISE EFFECTIVE REMEDIES AGAINST ARTHUR ANDERSEN LLP IN ANY LEGAL ACTION.

Our former independent public accountant, Arthur Andersen LLP, provided us with auditing services for prior fiscal periods through December 31, 2001, including issuing an audit report with respect to our audited consolidated financial statements as of and for the year ended December 31, 2001, which report is included in our annual report on Form 10-K for the year ended December 31, 2003. On June 15, 2002, a jury in Houston, Texas

found Arthur Andersen LLP guilty of a federal obstruction of justice charge arising from the federal government's investigation of Enron Corp. On August 31, 2002, Arthur Andersen LLP ceased practicing before the Securities and Exchange Commission.

We were unable to obtain Arthur Andersen LLP's consent to include its

report with respect to our audited consolidated financial statements as of and for the year ended December 31, 2001, in our annual report on Form 10-K for the year ended December 31, 2003. As a result, you may not have an effective remedy against Arthur Andersen LLP in connection with a material misstatement or omission with respect to those audited consolidated financial statements or any filing that we may make with the Securities and Exchange Commission. In addition, even if you were able to assert such a claim, as a result of its conviction and other lawsuits, Arthur Andersen LLP may fail or otherwise have insufficient assets to satisfy claims made by investors or by us that might arise under federal securities laws or otherwise relating to any alleged material misstatement or omission with respect to our audited consolidated financial statements.

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

WE ARE DEPENDING HEAVILY ON THE SUCCESS OF OUR LEAD PRODUCTS, HYB2055, OUR LEAD 2ND GENERATION IMO COMPOUND, AND GEM231, OUR LEAD 2ND GENERATION ANTISENSE COMPOUND, WHICH ARE IN CLINICAL DEVELOPMENT. IF WE ARE UNABLE TO COMMERCIALIZE EITHER OR BOTH OF THESE PRODUCTS, OR EXPERIENCE SIGNIFICANT DELAYS IN DOING SO, OUR BUSINESS WILL BE MATERIALLY HARMED.

We are investing a significant portion of our time and financial resources in the development of our two lead internal products, HYB2055, our lead 2nd generation IMO compound, and GEM 231, our lead 2nd generation antisense compound. We anticipate that in the near term our ability to generate product revenues will depend heavily on the successful development and commercialization of these products. The commercial success of these products will depend on several factors, including the following:

- successful completion of clinical trials;
- receipt of marketing approvals from the United States Food and Drug Administration, or FDA, and similar foreign regulatory authorities;
- establishing commercial manufacturing arrangements with third party manufacturers;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product in the medical community and with third party payors.

Our efforts to commercialize these products are at an early stage, as we are currently conducting phase 1 and phase 1/2 clinical trials of these product candidates. If we are not successful in commercializing either or both of these products, or are significantly delayed in doing so, our business will be materially harmed.

IF OUR CLINICAL TRIALS ARE UNSUCCESSFUL, OR IF THEY ARE SIGNIFICANTLY DELAYED, WE MAY NOT BE ABLE TO DEVELOP AND COMMERCIALIZE OUR PRODUCTS.

We may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show our potential products to be both safe and efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

In order to obtain regulatory approvals for the commercial sale of our products, we will be required to complete extensive clinical trials in humans to

demonstrate the safety and efficacy of our drug candidates. In 2003, we commenced phase 1 clinical trials of HYB2055, in oncology patients and in healthy volunteers, and we are currently conducting a phase 1/2 clinical trial of GEM231, for the treatment of solid tumor cancer. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to complete these trials or commence and complete any other clinical trials.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our products, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate; and
- the effects of our products may not be the desired effects or may include undesirable side effects or the products may have other unexpected characteristics.

As an example, in 1997, after reviewing the results from the clinical trial of GEM91, our lead 1st generation antisense compound at the time, we determined not to continue the development of GEM91 and suspended clinical trials of this product candidate.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. Patient accrual is a function of many factors, including:

- the size of the patient population,
- the proximity of patients to clinical sites,
- the eligibility criteria for the study,
- the nature of the study,
- the existence of competitive clinical trials, and

- the availability of alternative treatments.

Our product development costs will increase if we experience delays in our clinical trials. We do not know whether planned clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products.

WE FACE SUBSTANTIAL COMPETITION WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING DRUGS BEFORE OR MORE SUCCESSFULLY THAN US.

The biotechnology industry is highly competitive and characterized by rapid and significant technological change. We face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products, that are competitive with our product candidates in the therapeutic effect these competitive products have

on diseases targeted by our product candidates. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced than we are in drug discovery, development and commercialization, obtaining regulatory approvals and drug manufacturing and marketing.

We anticipate that the competition with our products and technologies will be based on a number of factors including:

- product efficacy,
- safety,
- reliability,
- availability,
- price and
- patent position.

The timing of market introduction of our products and competitive products will also affect competition among products. We also expect the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market to be an important competitive factor. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes and to secure sufficient capital resources for the period between technological conception and commercial sales.

BECAUSE THE PRODUCTS THAT WE MAY DEVELOP WILL BE BASED ON NEW TECHNOLOGIES AND THERAPEUTIC APPROACHES, THE MARKET MAY NOT BE RECEPTIVE TO THESE PRODUCTS UPON THEIR INTRODUCTION.

The commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. Many of the products that we are developing are based upon technologies or therapeutic approaches that are relatively new and unproven. The FDA has not granted marketing approval to any products based on antisense technology or IMO-like technology and no such products are currently being marketed, except for one antisense product that is currently being marketed by another company for the treatment of cytomegalovirus retinitis, an infectious disease, in patients with AIDs. As a result, it may be more difficult for us to achieve market acceptance of our products. Our efforts to educate the medical community on these potentially unique approaches may require greater resources than would be typically required for products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience and cost-effectiveness of our products as compared to competitive products will also affect market acceptance.

COMPETITION FOR TECHNICAL AND MANAGEMENT PERSONNEL IS INTENSE IN OUR INDUSTRY AND WE MAY NOT BE ABLE TO SUSTAIN OUR OPERATIONS OR GROW IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY PERSONNEL.

Our success is highly dependent on the retention of principal members of our technical and management staff, including Stephen Seiler and Sudhir Agrawal. Mr. Seiler, our Chief Executive Officer, has extensive experience in the pharmaceutical industry and as an investment banker and provides strategic leadership for us. The loss of Mr. Seiler's services would be detrimental to the execution of our strategic plan. Dr. Agrawal serves as our President and Chief Scientific Officer. Dr. Agrawal has made significant contributions to the field of nucleic acid chemistry and is named as an inventor on over 200 U.S. patents and patent applications. Dr. Agrawal provides the scientific leadership for our research and development activities and directly supervises our research staff. The loss of Dr. Agrawal's services would be detrimental to our ongoing scientific progress.

We are a party to employment agreements with each of Mr. Seiler and Dr. Agrawal, but each of these agreements may be terminated by us or the employee for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Mr. Seiler or Dr. Agrawal.

Furthermore, our future growth will require hiring a significant number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

REGULATORY RISKS

WE MAY NOT BE ABLE TO OBTAIN MARKETING APPROVAL FOR PRODUCTS RESULTING FROM OUR DEVELOPMENT EFFORTS.

All of the products that we are developing or may develop in the future will require additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This

process is lengthy, often taking a number of years, is uncertain and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. In 1997, we determined not to continue clinical development of GEM91, our lead product candidate at the time. Currently, we are conducting clinical trials of two compounds, GEM231 and HYB2055.

We may need to address a number of technological challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

WE ARE SUBJECT TO COMPREHENSIVE REGULATORY REQUIREMENTS, WHICH ARE COSTLY AND TIME CONSUMING TO COMPLY WITH; IF WE FAIL TO COMPLY WITH THESE REQUIREMENTS, WE COULD BE SUBJECT TO ADVERSE CONSEQUENCES AND PENALTIES.

The testing, manufacturing, labeling, advertising, promotion, export and marketing of our products are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

In general, submission of materials requesting permission to conduct clinical trials may not result in authorization by the FDA or any equivalent foreign regulatory agency to commence clinical trials. In addition, submission of an application for marketing approval to the relevant regulatory agency following completion of clinical trials may not result in the regulatory agency approving the application if applicable regulatory criteria are not satisfied, and may result in the regulatory agency requiring additional testing or information.

Any regulatory approval of a product may contain limitations on the indicated uses for which the product may be marketed or requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any product for which we obtain marketing approval, along with the facilities at which the product is manufactured, any post-approval clinical data and any advertising and promotional activities for the product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies.

Both before and after approval is obtained, violations of regulatory requirements may result in:

- the regulatory agency's delay in approving, or refusal to approve, an application for approval of a product;
- restrictions on such products or the manufacturing of such products;
- withdrawal of the products from the market;
- warning letters;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizure;

- refusal to permit the import or export of our products;
- injunctions or the imposition of civil penalties; and
- criminal penalties.

WE HAVE ONLY LIMITED EXPERIENCE IN REGULATORY AFFAIRS AND OUR PRODUCTS ARE BASED ON NEW TECHNOLOGIES; THESE FACTORS MAY AFFECT OUR ABILITY OR THE TIME WE REQUIRE TO OBTAIN NECESSARY REGULATORY APPROVALS.

We have only limited experience in filing the applications necessary to gain regulatory approvals. Moreover, the products that result from our research and development programs will likely be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional drugs. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any product that we develop.

RISKS RELATING TO COLLABORATORS

WE NEED TO ESTABLISH COLLABORATIVE RELATIONSHIPS IN ORDER TO SUCCEED.

An important element of our business strategy includes entering into collaborative relationships for the development and commercialization of products based on our discoveries. We face significant competition in seeking appropriate collaborators. Moreover, these arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish collaborative relationships or other alternative arrangements.

The success of collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. The risks that we face in connection with these collaborations include the following:

- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;
- disagreements with collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if one of our collaborators fails to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- collaborators have considerable discretion in electing whether to pursue the development of any additional drugs and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies or products that are the subject of the collaboration with us; and
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have

been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products.

Given these risks, it is possible that any collaborative arrangements into which we enter may not be successful. Previous collaborative arrangements to which we were a party with F. Hoffmann-La Roche and G.D. Searle & Co. both were terminated prior to the development of any product. The failure of any of our collaborative relationships could delay our drug development or impair commercialization of our products.

RISKS RELATING TO INTELLECTUAL PROPERTY

IF WE ARE UNABLE TO OBTAIN PATENT PROTECTION FOR OUR DISCOVERIES, THE VALUE OF OUR TECHNOLOGY AND PRODUCTS WILL BE ADVERSELY AFFECTED.

Our patent positions, and those of other drug discovery companies, are generally uncertain and involve complex legal, scientific and factual questions.

Our ability to develop and commercialize drugs depends in significant part on our ability to:

- obtain patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect trade secrets.

We do not know whether any of our patent applications or those patent applications which we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

THIRD PARTIES MAY OWN OR CONTROL PATENTS OR PATENT APPLICATIONS AND REQUIRE US TO SEEK LICENSES, WHICH COULD INCREASE OUR DEVELOPMENT AND COMMERCIALIZATION COSTS, OR PREVENT US FROM DEVELOPING OR MARKETING PRODUCTS.

We may not have rights under some patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third party patents issued in the United States and abroad or under patents that might issue from United States and foreign patent applications. In such event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

WE MAY LOSE OUR RIGHTS TO PATENTS, PATENT APPLICATIONS OR TECHNOLOGIES OF THIRD PARTIES IF OUR LICENSES FROM THESE THIRD PARTIES ARE TERMINATED. IN SUCH EVENT, WE MIGHT NOT BE ABLE TO DEVELOP OR COMMERCIALIZE PRODUCTS COVERED BY THE LICENSES.

We are party to 12 royalty-bearing license agreements under which we have acquired rights to patents, patent applications and technology of third parties. Under these licenses we are obligated to pay royalties on net

sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance and other obligations on us. Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2006 to 2021. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

WE MAY BECOME INVOLVED IN EXPENSIVE PATENT LITIGATION OR OTHER PROCEEDINGS, WHICH COULD RESULT IN OUR INCURRING SUBSTANTIAL COSTS AND EXPENSES OR SUBSTANTIAL LIABILITY FOR DAMAGES OR REQUIRE US TO STOP OUR DEVELOPMENT AND COMMERCIALIZATION EFFORTS.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not practicing and do not intend to practice any of the intellectual property involved in the proceedings. For instance, in 2002, we became involved in an interference declared by the United States Patent and Trademark Office involving a patent application exclusively licensed by us from University of Massachusetts Medical Center, or UMMC, and three patents issued to the National Institutes of Health. In addition, in 2003, we became involved in an interference declared by the United States Patent and Trademark Office involving another patent exclusively licensed to us from UMMC and a patent application assigned jointly to the University of Montreal and The Massachusetts Institute of Technology.

The cost to us of any patent litigation or other proceeding, including the interferences referred to above, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from

developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

RISKS RELATING TO PRODUCT MANUFACTURING, MARKETING AND SALES AND RELIANCE ON THIRD PARTIES

BECAUSE WE HAVE LIMITED MANUFACTURING EXPERIENCE, WE ARE DEPENDENT ON THIRD-PARTY MANUFACTURERS TO MANUFACTURE PRODUCTS FOR US. IF WE CANNOT RELY ON THIRD-PARTY MANUFACTURERS, WE WILL BE REQUIRED TO INCUR SIGNIFICANT COSTS AND DEVOTE SIGNIFICANT EFFORTS TO ESTABLISH OUR OWN MANUFACTURING FACILITIES AND CAPABILITIES.

We have limited manufacturing experience and no commercial scale manufacturing capabilities. In order to continue to develop our products, apply for regulatory approvals and ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties to produce materials that may be required for the commercial production of our products.

There are a limited number of manufacturers that operate under the FDA's current good manufacturing practices regulations capable of manufacturing our products. As a result, we may have difficulty finding manufacturers for our products with adequate capacity for our needs. If we are unable to arrange for third party manufacturing of our products on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance,
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control,
- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us,
- the potential that third party manufacturers will develop know-how owned by such third party in connection with the production of our products that is necessary for the manufacture of our products, and
- reliance upon third party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Between September 2000 and March 2004, we purchased oligonucleotides for preclinical and clinical testing from Avecia Biotechnology. In March 2004,

our manufacturing agreement with Avecia expired. We are seeking to renew our manufacturing agreement with Avecia. If we are unable to renew this agreement on satisfactory terms or on a timely basis, we may need to seek a new contract manufacturer. If we are unable to enter into a new manufacturing arrangement with Avecia or a new contract manufacturer on a timely basis or at all, our ability to supply the product needed for our clinical trials could be materially impaired.

WE HAVE NO EXPERIENCE SELLING, MARKETING OR DISTRIBUTING PRODUCTS AND NO INTERNAL CAPABILITY TO DO SO.

If we receive regulatory approval to commence commercial sales of any of our products, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we have no experience. To market any of our products directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. In particular, we would need to recruit a large number of experienced marketing and sales personnel. Alternatively, we could engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. However, to the extent we entered into such arrangements, we would be dependent on the efforts of third parties. If we are unable to establish sales and distribution capabilities, whether internally or in reliance on third parties, our business would suffer materially.

IF THIRD PARTIES ON WHOM WE RELY FOR CLINICAL TRIALS DO NOT PERFORM AS CONTRACTUALLY REQUIRED OR AS WE EXPECT, WE MAY NOT BE ABLE TO OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCTS, AND OUR BUSINESS MAY SUFFER.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers in the conduct of the clinical trials of our products and expect to continue to do so. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

IF WE ARE UNABLE TO OBTAIN ADEQUATE REIMBURSEMENT FROM THIRD PARTY PAYORS FOR ANY PRODUCTS THAT WE MAY DEVELOP OR ACCEPTABLE PRICES FOR THOSE PRODUCTS, OUR REVENUES AND PROSPECTS FOR PROFITABILITY WILL SUFFER.

Most patients will rely on Medicare and Medicaid, private health insurers and other third party payors to pay for their medical needs, including any drugs we may market. If third party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. The Congress recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program,

our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products.

Third party payors are challenging the prices charged for medical products and services, and many third party payors limit reimbursement for newly-approved healthcare products. In particular, third party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

WE FACE A RISK OF PRODUCT LIABILITY CLAIMS AND MAY NOT BE ABLE TO OBTAIN INSURANCE.

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing and marketing of human therapeutic drugs. Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

RISKS RELATING TO AN INVESTMENT IN OUR COMMON STOCK

OUR CORPORATE GOVERNANCE STRUCTURE, INCLUDING PROVISIONS IN OUR CERTIFICATE OF INCORPORATION AND BY-LAWS, OUR STOCKHOLDER RIGHTS PLAN AND DELAWARE LAW, MAY PREVENT A CHANGE IN CONTROL OR MANAGEMENT THAT STOCKHOLDERS MAY CONSIDER DESIRABLE.

Section 203 of the Delaware General Corporation Law and our certificate of incorporation, by-laws and stockholder rights plan contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

- a classified board of directors,
- limitations on the removal of directors,
- limitations on stockholder proposals at meetings of stockholders,
- the inability of stockholders to act by written consent or to call special meetings, and
- the ability of our board of directors to designate the terms

of and issue new series of preferred stock without stockholder approval.

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

OUR STOCK PRICE HAS BEEN AND MAY IN THE FUTURE BE EXTREMELY VOLATILE. IN ADDITION, BECAUSE AN ACTIVE TRADING MARKET FOR OUR COMMON STOCK HAS NOT DEVELOPED, OUR INVESTORS' ABILITY TO TRADE OUR COMMON STOCK MAY BE LIMITED. AS A RESULT, INVESTORS MAY LOSE ALL OR A SIGNIFICANT PORTION OF THEIR INVESTMENT.

Our stock price has been volatile. During the period from January 1, 2002 to April 1, 2004, the closing sale price of our common stock ranged from a high of $1.85 per share to a low of $0.60 per share. The stock market has also experienced significant price and volume fluctuations, and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- the regulatory status of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- the success of competitive products or technologies;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; and
- general economic, industry and market conditions.

In addition, our common stock has historically been traded at low volume levels and may continue to trade at low volume levels. As a result, any large purchase or sale of our common stock could have a significant impact on the price of our common stock and it may be difficult for investors to sell our common stock in the market without depressing the market price for the common stock or at all.

As a result of the foregoing, investors may not be able to resell their shares at or above the price they paid for such shares. Investors in our common stock must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of their investment in our stock could decline.

ITEM 7: FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS

1.1	Placement Agency Agreement, dated April 15, 2004, by and among the Company, Thomas Weisel Partners LLC, Rodman & Renshaw and Merriman Curham Ford & Co., including as Exhibit B thereto the form of Purchase Agreement to be entered into by the Company and the investors.
4.1	Form of Warrant.
5.1	Opinion of Hale and Dorr LLP.
23.1	Consent of Hale and Dorr LLP (included in Exhibit 5.1).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 15, 2004

HYBRIDON, INC.

/s/ Robert G. Andersen

Robert G. Andersen
Chief Financial Officer and
Vice President of Operations

EXHIBIT INDEX

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