Geovax Labs, Inc. Form 424B3 April 03, 2009

Prospectus Supplement No. 3 to Prospectus dated July 1, 2008

Filed Pursuant to Rule 424(b)(3) Registration Statement No. 333-151491

#### **GEOVAX LABS, INC.**

40,161,020 Shares of Common Stock

We are supplementing the prospectus dated July 1, 2008 covering the sale of up to 40,161,020 shares of our common stock, \$0.001 par value, by Fusion Capital Fund II, LLC to add certain information contained in our Annual Report on Form 10-K for the year ended December 31, 2008, which was filed with the Securities and Exchange Commission on March 12, 2009.

This prospectus supplements information contained in the prospectus dated July 1, 2008, as supplemented by Prospectus Supplement No. 1 dated August 26, 2008 and Prospectus Supplement No. 2 dated November 12, 2008. This prospectus supplement should be read in conjunction with the prospectus dated July 1, 2008, including any previous supplements and amendments thereto, which are to be delivered with this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus dated July 1, 2008, including any previous supplements and amendments thereto.

Investing in our common stock involves certain risks. See Risk Factors beginning on the following page of this prospectus supplement for a discussion of these risks.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement is April 2, 2009.

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#### Item 1A. Risk Factors

We face a number of substantial risks. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. The following factors should be considered in connection with the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes.

#### Risks Related to Our Financial Results and Need for Additional Financing

We have a history of operating losses, and we expect losses to continue for the foreseeable future.

Our ability to generate revenue and achieve profitability depends on our ability to complete successfully the development of our product candidates, conduct preclinical tests and clinical trials, obtain the necessary regulatory approvals and manufacture and market the resulting products. We have had no product revenue to date. We have experienced operating losses since we began operations in 2001. As of December 31, 2008, we had an accumulated deficit of approximately \$14.3 million. We expect to incur additional operating losses and expect cumulative losses to increase as our research and development, preclinical, clinical, manufacturing and marketing efforts expand.

Our business will require continued funding. If we do not receive adequate funding, we will not be able to continue our operations.

To date, we have financed our operations principally through the private placement of equity securities and through government grants. We will require substantial additional financing at various intervals for our operations, including for clinical trials, for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals and for establishing or contracting out manufacturing, marketing and sales functions. There is no assurance that such additional funding will be available on terms acceptable to us or at all. If we are not able to secure the significant funding that is required to maintain and continue our operations at current levels or at levels that may be required in the future, we may be required to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to some of our products or potential markets.

On May 8, 2008, we entered into a common stock purchase agreement ( Purchase Agreement ) with Fusion Capital Fund II, LLC, an Illinois limited liability company ( Fusion Capital ). Under the Purchase

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Agreement, Fusion Capital is obligated, under certain conditions, to purchase shares from us in an aggregate amount of up to \$10.0 million from time to time over a twenty-five (25) month period.

We only have the right to receive \$80,000 every 4 business days under the agreement with Fusion Capital unless the market price of our stock equals or exceeds \$0.11, in which case we can sell greater amounts to Fusion Capital as the market price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than \$0.05. We registered a total of 35.0 million of our shares for sale to Fusion Capital, of which approximately 28.9 million remain at March 10, 2009. Our sale price of these shares to Fusion Capital will have to average at least \$0.321 per share for us to receive the maximum remaining proceeds of \$9.26 million. Depending on the prevailing market price of our common stock and its trading volume, we may be unable to access the full remaining amount available from Fusion Capital prior to expiration of the Purchase Agreement, unless we choose to register and sell more shares, which we have the right, but not the obligation, to do. Subject to approval by our Board of Directors, we have the right but not the obligation to sell more than 35.0 million shares to Fusion Capital. In the event we elect to sell more than 35.0 million shares, we will be required to file a new registration statement and have it declared effective by the U.S. Securities & Exchange Commission.

The extent we rely on Fusion Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, such as through the sale of our products. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business days that the stock sale price of our common stock is less than \$0.05. If sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$10.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

## The current economic downturn may adversely impact our ability to raise capital.

The recent economic downturn and adverse conditions in the national and global markets may negatively affect our operations in the future. The falling equity markets and adverse credit markets may make it difficult for us to raise capital or procure credit in the future to fund the growth of our business, which could have a negative impact on our business and results of operations.

#### Risks Related to Development and Commercialization of Product Candidates and Dependence on Third Parties

#### Our products are still being developed and are unproven. These products may not be successful.

In order to become profitable, we must generate revenue through sales of our products, however our products are in varying stages of development and testing. Our products have not been proven in human research trials and have not been approved by any government agency for sale. Furthermore, if we enter into an agreement with Vivalis, our collaboration may not result in a commercially advantageous method for producing our MVA vaccine component. If we cannot successfully develop and prove our products and processes, and if we do not develop other sources of revenue, we will not become profitable and at some point we would discontinue operations.

We have sold no products or generated any product revenues and we do not anticipate any significant revenues to be generated in the foreseeable future.

We have conducted pre-clinical trials and are conducting clinical trials and will continue to do so for several more years before we are able to commercialize our technology. Although we have recognized

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revenues from government grants, there can be no assurance that we will ever generate significant product revenues.

Whether we are successful will be dependent, in part, upon the leadership provided by our management. If we were to lose the services of any of these individuals, our business and operations may be adversely affected.

Whether our business will be successful will be dependent, in part, upon the leadership provided by our officers, particularly our President and Chief Executive Officer, members of our Board of Directors and our primary scientist. The loss of the services of these individuals may have an adverse effect on our operations.

Regulatory and legal uncertainties could result in significant costs or otherwise harm our business.

In order to manufacture and sell our products, we must comply with extensive international and domestic regulation. In order to sell our products in the United States, approval from the FDA is required. The FDA approval process is expensive and time-consuming. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to meet than FDA requirements. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long-term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

We will face intense competition and rapid technological change that could result in products that are superior to the products we will be commercializing or developing.

The market for vaccines that protect against HIV/AIDS is intensely competitive and is subject to rapid and significant technological change. We will have numerous competitors in the United States and abroad, including, among others, large companies with substantially greater resources than us. These competitors may develop technologies and products that are more effective or less costly than any of our future products or that could render our products obsolete or noncompetitive. We expect most of these competitors to have substantially more resources than us. In addition, the pharmaceutical industry continues to experience consolidation, resulting in an increasing number of larger, more diversified companies than us. Among other things, these companies can spread their research and development costs over much broader revenue bases than we can and can influence customer and distributor buying decisions.

Our products may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Significant factors in determining whether we will be able to compete successfully include:

the efficacy and safety of our vaccines;

the time and scope of regulatory approval;

reimbursement coverage from insurance companies and others;

the price and cost-effectiveness of our products; and

patent protection.

Our product candidates are based on new technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals or that our product candidates will be hard to manufacture on a large scale or will be uneconomical to market.

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Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal additional complications associated with our products. The responses of potential physicians and others to information about complications could materially affect the market acceptance of our products, which in turn would materially harm our business.

Because we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.

We cannot commercialize any of our product candidates until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. The regulatory agencies may not complete their review processes in a timely manner and we may not obtain regulatory approval for any product candidate we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, if approval is obtained at all, is dependent upon the type, complexity and novelty of the product, and requires the expenditure of substantial resources. Regulatory approval processes outside the United States may include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We may experience delays in our clinical trials that could adversely affect our financial results and our commercial prospects.

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule or at all. Product development costs will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products, and delay our ability to become profitable.

We rely heavily on the HIV Vaccine Trials Network (HVTN), independent clinical investigators, and other third party service providers 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 and recording and reporting the results of 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 product candidates.

Unsuccessful or delayed regulatory approvals required to exploit the commercial potential of our products could increase our future development costs or impair our future sales.

None of our products or technologies have been approved by the FDA for sales in the United States or in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials would prevent regulatory approval and restrict our ability to commercialize our

technologies. Any such failure may severely harm our business. In addition, any approvals we obtain may not cover all of the clinical indications for which approval is sought, or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications

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with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

In recent years, several states, including California, Vermont, Maine, Minnesota, New Mexico and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties and could receive adverse publicity, all of which could harm our business.

We may be subject to new federal and state legislation to submit information on our open and completed clinical trials to public registries and databases.

In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act, or the FDMA, in order to promote public awareness of and access to these clinical trials. Under the FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of trials included in this or other registries, as well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those trials that have been registered with a no-cost, publicly accessible database, such as www.clinicaltrials.gov. Federal legislation was introduced in the fall of 2004 to expand www.clinicaltrials.gov and to require the inclusion of study results in this registry. The Pharmaceutical Research and Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical studies publicly available and has established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. Failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines and other penalties, all of which could materially harm our business.

#### We will face uncertainty related to pricing and reimbursement and health care reform.

In both domestic and foreign markets, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payers is presently undergoing reform and there is significant uncertainty at this time how this will affect sales of certain pharmaceutical products.

Medicare, Medicaid and other governmental healthcare programs govern drug coverage and reimbursement levels in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. Generic drug manufacturers—agreements with federal and state governments provide that the manufacturer will remit to each state Medicaid agency, on a quarterly basis, 11% of the average manufacturer price for generic products marketed and sold under abbreviated new drug applications covered by the state—s Medicaid program. For proprietary products, which are marketed and sold under new drug applications, manufacturers are required to rebate the greater of (a) 15.1% of the average manufacturer price or (b) the difference between the average manufacturer price and the lowest manufacturer price for products sold during a specified period.

Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for

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any product developed in the future. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, some uncertainty may exist as to the reimbursement status of newly approved injectable pharmaceutical products. Our products may not be considered cost effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

We may not be successful in establishing collaborations for product candidates we may seek to commercialize, which could adversely affect our ability to discover, develop and commercialize products.

We expect to seek collaborations for the development and commercialization of product candidates in the future. The timing and terms of any collaboration will depend on the evaluation by prospective collaborators of the trial results and other aspects of our vaccine s safety and efficacy profile. If we are unable to reach agreements with suitable collaborators for any product candidate, we would be forced to fund the entire development and commercialization of such product candidates, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration early in the development of a product candidate, we may be forced to accept a more limited share of any revenues this product may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for any product candidate. Even if we are successful in establishing collaborations, we may not be able to ensure fulfillment by collaborators of their obligations or our expectations.

# We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.

We do not have experience in marketing or selling vaccines. We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our products. To obtain the expertise necessary to successfully market and sell our vaccines, will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize our vaccines in the United States or elsewhere.

#### We may be required to defend lawsuits or pay damages for product liability claims.

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. We carry product liability insurance and we expect to continue such policies. Product liability claims, regardless of their merits, could exceed policy limits, divert management s attention, and adversely affect our reputation and the demand for our products.

#### **Risks Related to Our Intellectual Property**

Other parties may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products.

Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary

rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies which market generic products focus their development efforts on products with expiring patents. Pharmaceutical companies, biotechnology companies, universities, research institutions or other third parties

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may have filed patent applications or may have been granted patents that cover aspects of our products or our licensors products, product candidates or other technologies.

Future or existing patents issued to third parties may contain patent claims that conflict with our products. We expect to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against us in the future with respect to our current products or with respect to products that we may develop or license. Litigation or interference proceedings could force us to:

stop or delay selling, manufacturing or using products that incorporate or are made using the challenged intellectual property;

pay damages; or

enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any litigation or interference proceedings, regardless of their outcome, would likely delay the regulatory approval process, be costly and require significant time and attention of our key management and technical personnel.

Any inability to protect intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell products.

We will rely on trade secrets, unpatented proprietary know-how, continuing technological innovation and, in some cases, patent protection to preserve a competitive position. Our patents and licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents, or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies.

We may not be able to prevent third parties from infringing or using our intellectual property, and the parties from whom we may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property. We generally will attempt to control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite efforts to protect this proprietary information, however, unauthorized parties may obtain and use information that we may regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to these technologies.

The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

The U.S. Patent and Trademark Office and the courts have not established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

#### Risks Related to Our Common Stock

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

In connection with entering into the common stock purchase agreement with Fusion Capital, we authorized the sale to Fusion Capital of up to 35.0 million shares of our common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant

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to the common stock purchase agreement will fluctuate based on the price of our common stock. Depending upon market liquidity at the time, a sale of shares by Fusion Capital at any given time could cause the trading price of our common stock to decline. Sales to Fusion Capital by us under the agreement may result in substantial dilution to the interests of other holders of our common stock.

#### The agreement with Fusion Capital may adversely impact our other fundraising initiatives.

The sale of a substantial number of shares of our common stock under our arrangement with Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

### The market price of our common stock is highly volatile.

The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by shareholders and by the Company, and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

# Our common stock is and likely will remain subject to the SEC s Penny Stock rules, which may make our shares more difficult to sell.

Because the price of our common stock is currently and may remain less than \$5.00 per share, it is classified as a penny stock. The SEC rules regarding penny stocks may have the effect of reducing trading activity in our shares, making it more difficult for investors to sell. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

make a special written suitability determination for the purchaser;

receive the purchaser s written agreement to a transaction prior to sale;

provide the purchaser with risk disclosure documents which identify certain risks associated with investing in penny stocks and which describe the market for these penny stocks as well as a purchaser s legal remedies;

obtain a signed and dated acknowledgement from the purchaser demonstrating that the purchaser has received the required risk disclosure document before a transaction in a penny stock can be completed; and

give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation.

These rules make it more difficult for broker-dealers to effectuate customer transactions and trading activity in our securities and may result in a lower trading volume of our common stock and lower trading prices.

#### Item 6. Selected Financial Data

The following selected financial data are derived from our audited consolidated financial statements. The historical results presented below are not necessarily indicative of the results to be expected for any future period. You should read the information set forth below in conjunction with the information contained in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations , and our consolidated financial statements and the related notes, beginning on page F-1 of this Report.

	2008	2007	2006	2005	2004
Statement of Operations					
Data:					
Total revenues (grant					
income)	\$ 2,910,170	\$ 237,004	\$ 852,905	\$ 670,467	\$ 714,852
Net loss	(3,728,187)	(4,241,796)	(584,166)	(1,611,086)	(2,351,828)
Basic and diluted net loss per					
common share	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)
Balance Sheet Data:					
Total assets	3,056,241	3,246,404	2,396,330	1,685,218	1,870,089
Redeemable convertible					
preferred stock				1,016,555	938,475
Total stockholders equity					
(deficit)	2,709,819	2,647,866	2,203,216	(500,583)	(389,497)

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with the discussion under Selected Financial Data and our consolidated financial statements included in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties because they are based on current expectations and relate to future events and our future financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Risk Factors and elsewhere in this Annual Report.

#### Overview

GeoVax is a clinical stage biotechnology company focused on developing human vaccines for diseases caused by Human Immunodeficiency Virus and other infectious agents. We have exclusively licensed from Emory University certain HIV vaccine technology which was developed in collaboration with the National Institutes of Health and the Centers for Disease Control and Prevention.

Our HIV vaccine candidates have successfully completed preclinical efficacy testing in non-human primates and Phase 1 clinical testing trials in humans. A Phase 2a human clinical trial for our preventative HIV vaccine candidate was initiated during the fourth quarter of 2008, and patient enrollment commenced in February 2009. The costs of conducting our human clinical trials to date have been borne by HVTN, with GeoVax incurring costs associated with manufacturing the clinical vaccine supplies and other study support. HVTN will also bear the cost of conducting our Phase 2a human clinical study, but we can not predict the level of support we will receive from HVTN for any additional clinical studies. Our operations are also partially supported by an Integrated Preclinical/Clinical AIDS Vaccine Development [IPCAVD] Grant from the NIH. We expect this grant to provide approximately \$15 million

(approximately \$3 million awarded annually) to us over a five year period that began in October 2007. The grant is subject to annual renewal, with the latest grant award covering the period from September 2008 through August 2009. We intend to pursue additional grants from the federal government, however, as we progress to the later stages of our vaccine development activities, government financial support may be more difficult to obtain, or may not be available at all. It will, therefore, be necessary for us to look to other sources of funding in order to finance our development activities.

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We anticipate incurring additional losses for several years as we expand our drug development and clinical programs and proceed into higher cost human clinical trials. Conducting clinical trials for our vaccine candidates in development is a lengthy, time-consuming and expensive process. We do not expect to generate product sales from our development efforts for several years. If we are unable to successfully develop and market pharmaceutical products over the next several years, our business, financial condition and results of operations will be adversely impacted.

## **Critical Accounting Policies and Estimates**

Management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and adjusts the estimates as necessary. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are summarized in Note 2 to our consolidated financial statements. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Impairment of Long-Lived Assets. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future net cash flows expected to be generated by such assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the discounted expected future net cash flows from the assets.

Revenue Recognition. We recognize revenue in accordance with the SEC s Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, as amended by Staff Accounting Bulletin No. 104, Revenue Recognition, (SAB 104). SAB No. 104 provides guidance in applying U.S. generally accepted accounting principles to revenue recognition issues, and specifically addresses revenue recognition for upfront, nonrefundable fees received in connection with research collaboration agreements. Our revenue consists primarily of government grant revenue, which is recorded as income as the related costs are incurred.

Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payments (SFAS 123R), which requires the measurement and recognition of compensation expense for all share-based payments made to employees and directors based on estimated fair values on the grant date. SFAS 123R replaces SFAS 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. We adopted SFAS 123R using the prospective application method which requires us to apply the provisions of SFAS 123R prospectively to new awards and to awards modified, repurchased or cancelled after December 31, 2005. Awards granted after December 31, 2005 are valued at fair value in accordance with the provisions of SFAS 123R and recognized on a straight line basis over the service periods of each award.

## **Liquidity and Capital Resources**

At December 31, 2008, we had cash and cash equivalents of \$2,191,180 and total assets of \$3,056,241, as compared to \$1,990,356 and \$3,246,404, respectively, at December 31, 2007. Working capital totaled \$2,455,412 at December 31, 2008, compared to \$2,432,276 at December 31, 2007.

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Sources and Uses of Cash. We are a development-stage company and do not have any products approved for sale. Due to our significant research and development expenditures, we have not been profitable and have generated operating losses since our inception in 2001. Our primary sources of cash are from sales of our equity securities and from government grant funding.

Cash Flows from Operating Activities. Net cash used in operating activities was \$2,367,886, \$3,265,743 and \$1,327,941 for the years ended December 31, 2008, 2007 and 2006, respectively. Generally, the differences between years are due to fluctuations in our net losses which, in turn, result from fluctuations in expenditures from our research activities, offset by net changes in our assets and liabilities.

In September 2007, the National Institutes of Health (NIH) awarded us an Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant to support our HIV/AIDS vaccine program. The project period for the grant covers a five year period which commenced October 2007, with an award of approximately \$3 million per year, or \$15 million in the aggregate. We are utilizing this funding to further our HIV/AIDS vaccine development, optimization, and production for human clinical trial testing. The funding we receive pursuant to this grant is recorded as revenue at the time the related expenditures are incurred, and thus partially offsets our net losses.

Cash Flows from Investing Activities. Our investing activities have consisted predominantly of capital expenditures. Capital expenditures for the years ended December 31, 2008, 2007 and 2006, were \$99,831, \$-0-, and \$69,466, respectively.

Cash Flows from Financing Activities. Net cash provided by financing activities was \$2,668,541, \$3,167,950 and \$2,212,849 for the years ended December 31, 2008, 2007 and 2006, respectively. The cash generated by our financing activities generally relates to the sale of our common stock to individual accredited investors and to Fusion Capital, offset by costs associated with our financing arrangement with Fusion Capital (see below).

In May 2008, we signed the Purchase Agreement with Fusion Capital Fund II, LLC, an Illinois limited liability company (Fusion Capital) which provides for the sale of up to \$10 million of shares of our common stock. In connection with this agreement, we filed a registration statement related to the transaction with the SEC covering the shares that have been issued or may be issued to Fusion Capital under the Purchase Agreement. The SEC declared effective the registration statement on July 1, 2008, and we now have the right until July 1, 2010 to sell our shares of common stock to Fusion Capital from time to time in amounts ranging from \$80,000 to \$1 million per purchase transaction, depending on certain conditions as set forth in the Purchase Agreement. During 2008 we received \$500,000 from the sale of our common stock to Fusion Capital pursuant to this arrangement.

We believe that our current working capital, combined with the proceeds from the IPCAVD grant awarded annually from the NIH and our anticipated use of the Purchase Agreement with Fusion Capital, will be sufficient to support our planned level of operations through 2009 and into 2010. The extent to which we rely on the Purchase Agreement as a source of funding will depend on a number of factors including the prevailing market price of our common stock and the extent to which we can secure working capital from other sources if we choose to seek such other sources. Even if we are able to access the full \$10 million under the Purchase Agreement, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects. While we believe that we will be successful in obtaining the necessary financing to fund our operations through the Purchase Agreement or through other sources, there can be no assurances that such additional funding will be available to us on reasonable terms or at all.

Our capital requirements, particularly as they relate to product research and development, have been and will continue to be significant. We intend to seek FDA approval of our products, which may take several years. We will not generate revenues from the sale of our products for at least several years, if at all. We will be dependent on obtaining financing from third parties in order to maintain our operations, including our clinical program. Due to the existing uncertainty in the capital and credit markets, and adverse regional and

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national economic conditions which may persist or worsen, capital may not be available on terms acceptable to the Company or at all. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations, or to seek to merge with or to be acquired by another company.

We have no off-balance sheet arrangements that are likely or reasonably likely to have a material effect on our financial condition or results of operations.

#### **Contractual Obligations**

As of December 31, 2008, we had approximately \$203,000 of unrecorded contractual commitments associated with our vaccine manufacturing activities, for services expected to be rendered to us during 2009. As of that date, we had no other firm purchase obligations or commitments for capital expenditures, no committed lines of credit or other committed funding or long-term debt, and no lease obligations (operating or capital). We have employment agreements with our senior management team, each of which may be terminated with 30 days advance notice. We have no other contractual obligations, with the exception of commitments which are contingent upon the occurrence of future events.

In July 2008, we signed a non-binding letter of intent for a joint collaboration and commercial license for the use of vaccine manufacturing technology owned by Vivalis S.A., a French biopharmaceutical company. Subsequent to the signing of the letter of intent, we paid a signing fee of approximately \$241,000 to Vivalis, and upon execution of the final license agreement, we will incur a commitment of approximately \$900,000 as our contribution to the joint development effort in 2009 and early 2010. As the development milestone fees are denominated in Euros, this estimate of our financial commitment is based on current exchange rates; the actual amounts will be greater or lesser, depending on the actual exchange rates at the time of each milestone achievement.

### Net Operating Loss Carryforward

At December 31, 2008, we had consolidated net operating loss carryforwards for income tax purposes of \$70 million, which will expire in 2010 through 2028 if not utilized. Approximately \$59.7 million of our net operating loss carryforwards relate to the operations of the Company (Dauphin Technology, Inc.) prior to the Merger. We also have research and development tax credits of \$355,000 available to reduce income taxes, if any, which will expire in 2022 through 2027 if not utilized. The amount of net operating loss carryforwards and research tax credits available to reduce income taxes in any particular year may be limited in certain circumstances. Based on an assessment of all available evidence including, but not limited to, our limited operating history in our core business and lack of profitability, uncertainties of the commercial viability of our technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, we have concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred tax valuation allowance has been recorded against these assets.

#### **Results of Operations**

#### Net Loss

We recorded net losses of \$3,728,187, \$4,241,796 and \$584,166 for the years ended December 31, 2008, 2007 and 2006, respectively. Our operating results will typically fluctuate due to the timing of activities and related costs associated with our vaccine research and development activities and our general and administrative costs, as described in more detail below.

#### Grant Revenue

We recorded grant revenues of \$2,910,170 in 2008, \$237,004 in 2007 and \$852,905 in 2006. Grant revenue reported during 2006 relates to projects covered by grants from the National Institutes of Health issued to Emory University and subcontracted to us pursuant to collaborative arrangements with Emory University. The activities associated with these grants were completed during 2006. During 2007, we were

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awarded an Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) grant by the National Institutes of Health (NIH) to support our HIV/AIDS vaccine program. The project period for this grant covers a five year period which commenced during October 2007, with expected annual awards of between \$3-4 million, or approximately \$15-16 million in the aggregate. We are utilizing this funding to further our HIV/AIDS vaccine development, optimization and production. The grant is subject to annual renewal, with the latest grant award covering the period from September 2008 through August 2009. As of December 31, 2008, there is approximately \$3 million remaining from the current year s award and carryovers from the prior year award. Assuming that the remaining budgeted amounts under the grant are awarded to the Company, there is an additional \$10 million available through the grant. We expect to record between \$3.4 to \$3.6 million in revenues associated with the grant during 2009.

## Research and Development

Our research and development expenses were \$3,741,489 in 2008, \$1,757,125 in 2007 and \$665,863 in 2006. Research and development expenses vary considerably on a period-to-period basis, primarily depending on our need for vaccine manufacturing and testing of manufactured vaccine by third parties. Research and development expense includes stock-based compensation expense of \$494,041, \$284,113 and \$-0- for 2008, 2007 and 2006, respectively (see discussion below). Research and development costs increased during the 2007 and 2008 periods as a direct result of spending associated with the NIH grant discussed above, and due to costs associated with our vaccine manufacturing activities in preparation for commencement of Phase 2 clinical testing, as well as the addition of new scientific personnel. Our recently initiated Phase 2a clinical trial will be conducted and funded by the HVTN, but we are responsible for the manufacture of vaccine product to be used in the trial. We can not predict the level of support we may receive from HVTN or other federal agencies (or divisions thereof) for our future clinical trials. We expect that our research and development costs will continue to increase in 2009 and beyond as we progress through the human clinical trial process leading up to possible product approval by the FDA.

In July 2008, we signed a letter of intent with Vivalis S.A., a French biopharmaceutical company, for joint collaboration and license of Vivalis proprietary EB® technology. The letter of intent contemplates development of a process using the EBx® technology to manufacture the MVA component of the GeoVax HIV-1 vaccine. Vivalis vaccine manufacturing technology is based on a duck embryonic stem cell substrate platform, providing continuous growth from a fully characterized frozen cell bank without necessitating fertilized embryo extraction and processing, as with present chicken cell based technologies. Furthermore, the EB66® cell line can be grown in suspension (without the cells attached to the surface of the growth vessel) and can be scaled up for growth in giant bioreactors (a cutting edge industrial method) for large scale production of the MVA viral vaccine. We expect the final agreement with Vivalis to be executed during the first half of 2009. Subsequent to execution of this agreement, we expect to incur substantial costs associated with development of this vaccine manufacturing technology, with preliminary cost estimates ranging from \$1.5 to \$2.0 million during 2009 and early 2010.

#### General and Administrative Expense

Our general and administrative expenses were \$2,970,068 in 2008, \$2,784,182 in 2007 and \$843,335 in 2006. General and administrative costs have substantially increased during the three year period ending December 31, 2007 primarily as a result of the Company becoming a publicly-traded entity subsequent to the merger of GeoVax Labs, Inc and GeoVax, Inc. in September 2006. These higher costs include, among other things, the costs of an expanded management team (including the engagement of our Chief Financial Officer in October 2006 and our Senior Vice President in January 2007), a newly instituted investor relations program, costs associated with an expanded Board of Directors, costs associated with our efforts to comply with the Sarbanes-Oxley Act of 2002, and increased legal and accounting fees associated with compliance with securities laws. General and administrative expense includes stock-based compensation expense of \$1,525,008, \$1,234,380 and \$-0- for 2008, 2007 and 2006, respectively (see discussion below). We expect that general and administrative expenses may increase in the future in support of

expanded research and development activities.

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#### Stock-Based Compensation Expense

During 2008, we recorded total stock-based compensation expense of \$2,019,049, which was allocated to research and development expense (\$494,041), or general and administrative expense (\$1,525,008) according to the classification of cash compensation paid to the employee, consultant or director to whom the stock compensation was granted. During 2007, we recorded total stock-based compensation expense of \$1,518,496, of which \$284,113 was allocated to research and development expense and \$1,234,380 was allocated to general and administrative expense. No stock-based compensation expense was recorded during 2006. Stock-based compensation expense is calculated and recorded in accordance with the provisions of SFAS 123R. We adopted SFAS 123R using the prospective application method which requires us to apply its provisions prospectively to new awards and to awards modified, repurchased or cancelled after December 31, 2005. Awards granted after December 31, 2005 are valued at fair value in accordance with the provisions of SFAS 123R and recognized on a straight line basis over the service periods of each award. We did not grant or modify any share-based compensation during 2006, thus no expense was recorded during for that year.

#### Other Income

Interest income was \$73,200 in 2008, \$62,507 in 2007 and \$72,127 in 2006. The variances between years are primarily attributable to the cash available for investment, which totaled \$2,191,180 at December 31, 2008, \$1,990,356 at December 31, 2007 and \$2,088,149 at December 31, 2006.

#### Impact of Inflation

For the three year period ending December 31, 2008, we do not believe that inflation and changing prices had a material impact on our operations or on our financial results.

#### **Off-Balance Sheet Arrangements**

We have not entered into off-balance sheet financing arrangements, other than operating leases.

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# GEOVAX LABS, INC. (A DEVELOPMENT-STAGE ENTERPRISE)

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# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENTS

To the Board of Directors GeoVax Labs, Inc. Atlanta, Georgia

We have audited the accompanying consolidated balance sheet of GeoVax Labs, Inc. and subsidiary (a development stage company) (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders—equity, and cash flows for each of the three years in the period ended December 31, 2008, and for the period of time considered part of the development stage from January 1, 2006 to December 31, 2008, except we did not audit the Company—s financial statements for the period from June 27, 2001 to December 31, 2005 which were audited by other auditors. These financial statements are the responsibility of the Company—s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of GeoVax Labs, Inc. and subsidiary as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

Our audit of the consolidated financial statements also included the financial statement schedule of the Company, listed in Item 15(a) of this Form 10-K. This schedule is the responsibility of the Company s management. Our responsibility is to express an opinion based on our audit of the consolidated financial statements. In our opinion, the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), GeoVax Labs, Inc. and subsidiary s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control* Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 5, 2009, expressed an unqualified opinion on the effectiveness of GeoVax Labs, Inc. s internal control over financial reporting.

/s/ PORTER KEADLE MOORE LLP

Atlanta, Georgia March 5, 2009

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