DYNAVAX TECHNOLOGIES CORP
Form 424B5
October 24, 2013
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The information contained in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated October 24, 2013

PROSPECTUS SUPPLEMENT

(To Prospectus dated October 17, 2013)

Shares

Common Stock

We are offering shares of our common stock.

Our common stock trades on The NASDAQ Capital Market under the symbol DVAX . On October 23, 2013, the last reported sale price of our common stock on The NASDAQ Capital Market was $1.15 per share.

Concurrently with this offering of common stock and pursuant to a separate prospectus supplement, we are offering shares of our Series B Convertible Preferred Stock (and the common stock issuable from time to time upon conversion of the Series B Convertible Preferred Stock).

	Per share	*Total*
Public offering price	**$**	**$**
Underwriting discounts and commissions[(1)]	**$**	**$**
Proceeds to us, before expenses	**$**	**$**

(1) See Underwriting beginning on page S-28 for a description of the compensation payable to the underwriters.

Investing in our common stock involves a high degree of risk. See Risk Factors on page S-6 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock on or about October , 2013.

Sole Book-Running Manager

Cowen and Company

Co-Manager

William Blair

Prospectus Supplement dated October , 2013

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated October 17, 2013, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in or incorporated by reference into this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You also should read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement titled Where You Can Find More Information and Incorporation Of Certain Information By Reference.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement to Dynavax, we, our or similar references mean Dynavax Technologies Corporation and its subsidiaries.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement or the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering, including the information under the heading Risk Factors in this prospectus supplement on page S-6 and the documents incorporated by reference into this prospectus supplement.

The Company

Business Overview

We are a clinical-stage biopharmaceutical company that discovers and develops novel products to prevent and treat infectious and inflammatory diseases and cancer. Our lead product candidate is HEPLISAV , a hepatitis B vaccine product candidate in Phase 3 development.

In addition to HEPLISAV, our pipeline comprises clinical-stage product candidates including an autoimmune program partnered with GlaxoSmithKline, an asthma program partnered with AstraZeneca AB and a cancer immunotherapy program as well as a preclinical development program utilizing nanoparticle adjuvant technology. We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations in developing therapies to prevent or treat infectious and inflammatory diseases and cancer.

According to IMS HEALTH, the U.S. market for adult hepatitis B vaccines is approximately $270 million. We believe that the US market has the potential to double in size, if HEPLISAV is approved, primarily as a result of expanded use in diabetic patients along with the promotion of HEPLISAV and better compliance with a 2 dose regimen.

Recent Developments

Following discussions with the U.S. Food and Drug Administration (FDA), we recently finalized the design of a new clinical study of HEPLISAV, our investigational adult hepatitis B vaccine. Study HBV-23 is intended to provide a sufficiently-sized safety database for FDA to complete its review of Dynavax s Biologics License Application (BLA). It will be a Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV compared with Engerix-B® in adults 18 to 70 years of age. The study will include 5,500 HEPLISAV subjects and 2,500 Engerix-B subjects, stratified by age and diabetes diagnosis. HEPLISAV subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months.

The primary objectives of HBV-23 will be: (1) to evaluate the overall safety of HEPLISAV with respect to clinically significant adverse events and (2) to demonstrate the noninferiority of the peak seroprotection rate (SPR) induced by HEPLISAV versus Engerix-B in subjects with type 2 diabetes mellitus. All HEPLISAV subjects will be evaluated for safety for one year following the second dose and all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee. Immunogenicity assessments will be conducted in a subset of subjects, including those with type 2 diabetes. We intend to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015 and estimate the external costs of the study to be in the range of $50-55 million.

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In Europe, our Marketing Authorization Application for HEPLISAV is currently under review by the European Medicines Agency s (EMA). In late 2012, we received the 120-Day List of Questions which relate to Suitability of different patient populations, Safety database, Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) matters. In the early summer EMA added to the list of questions, resetting the clock for our response. EMA has also inspected some study sites, Dynavax and our clinical contract research organization. The focus of the GCP inspection was HBV-17, a 500 patient study in CKD patients that is part of the EMA application but not the US application. We are currently preparing our response to the 120-Day Questions and expect to submit the response before the end of 2014. EMA will consider our responses and in the first quarter of 2014 will issue the 180-Day List of Outstanding Issues (LOI). We anticipate that the discussion regarding the patient group who would most likely benefit, and some of the GMP/GCP matters will need to be resolved following issuance of the 180-Day LOI.

Corporate Information

We were incorporated in California in August 1996 under the name Double Helix Corporation, and we changed our name to Dynavax Technologies Corporation in September 1996. We reincorporated in Delaware in 2001. Our principal offices are located at 2929 Seventh Street, Suite 100, Berkeley, California 94710-2753. Our telephone number is (510) 848-5100. We maintain an Internet website at www.dynavax.com. Information contained on, or accessible through, our website does not constitute part of this prospectus supplement or the accompanying prospectus.

Concurrent Offering of Series B Convertible Preferred Stock

Concurrently with this offering of common stock, we are offering shares of our Series B Convertible Preferred Stock (and the common stock issuable from time to time upon conversion of the Series B Convertible Preferred Stock), which we refer to herein as the Series B Preferred Stock offering. The Series B Preferred Stock offering is being conducted as a separate public offering by means of a separate prospectus supplement. This offering is not contingent upon the completion of the Series B Preferred Stock offering and the Series B Preferred Stock offering is not contingent upon the completion of this offering. We cannot assure you that either or both of the offerings will be completed.

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The Offering

Issuer	Dynavax Technologies Corporation
Common stock offered by us in this offering	shares
Common stock to be outstanding immediately after this offering	shares
Use of proceeds	We intend to use the net proceeds from this offering and the concurrent Series B Preferred Stock offering primarily to fund development activities associated with conducting an additional Phase 3 study of HEPLISAV and seeking regulatory approval to commercialize the vaccine in the United States and Europe, and for other general corporate purposes, including working capital. See Use of Proceeds on page S-25 of this prospectus supplement.
Risk factors	Investing in our common stock involves a high degree of risk. See Risk Factors on page S-6 of this prospectus supplement and the documents incorporated by reference into this prospectus supplement.
NASDAQ Capital Market symbol	DVAX
Concurrent Series B Preferred Stock offering	Concurrently with this offering, we are offering shares of our Series B Convertible Preferred Stock (and the common stock issuable from time to time upon conversion of the Series B Convertible Preferred Stock). The Series B Preferred Stock offering is being conducted as a separate public offering by means of a separate prospectus supplement. This offering is not contingent upon the completion of the Series B Preferred Stock offering and the Series B Preferred Stock offering is not contingent upon the completion of this offering.

The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 182,987,918 shares outstanding as of June 30, 2013, and excludes as of that date:

- 12,463,973 shares of common stock issuable upon the exercise of warrants, having a weighted average exercise price of $1.96 per share;
- 17,621,510 shares of common stock issuable upon the exercise of stock options, having a weighted average exercise price of $3.19 per share;
- 1,660,000 unvested restricted stock units;

an aggregate of 12,251,371 shares of common stock reserved for future issuance under our stock option and employee stock purchase plans; and

shares of our Series B Convertible Preferred Stock being offered by us in connection with our concurrent Series B Preferred Stock offering.

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Summary Consolidated Financial Data

We present below a summary of certain of our historical consolidated financial data. We have derived our summary consolidated statements of operations data for the years ended December 31, 2012, 2011 and 2010 from our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012 and incorporated by reference in this prospectus supplement and the accompanying prospectus. We have derived our summary consolidated statements of operations data for the six months ended June 30, 2013, and our summary consolidated balance sheet data as of June 30, 2013, from our unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 and incorporated by reference in this prospectus supplement and the accompanying prospectus.

Our historical results are not necessarily indicative of the results to be expected in any future period. The following summary information should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included in our periodic reports on file with the SEC and incorporated by reference in this prospectus supplement and the accompanying prospectus.

	Six Months Ended June 30,		Years Ended December 31,		
	2013	2012	2012	2011	2010
	(Unaudited)		(In thousands, except per share data)		
Consolidated Statements of Operations Data:					
Total revenues	$ 5,477	$ 5,034	$ 9,714	$ 21,614	$ 23,950
Operating expenses:					
Research and development	26,969	23,781	49,146	51,322	53,680
General and administrative	16,436	11,750	28,164	17,570	16,879
Amortization of intangible assets				299	980
Total operating expenses	43,405	35,531	77,310	69,191	71,539
Loss from operations	(37,928)	(30,497)	(67,596)	(47,577)	(47,589)
Interest income	126	117	291	103	85
Interest expense	(59)	(1,176)	(2,351)	(1,957)	(1,654)
Other income (expense)[1]	(128)	(59)	(293)	834	(8,150)
Net loss	(37,989)	(31,615)	(69,949)	(48,597)	(57,308)
Basic and diluted net loss per share attributable to Dynavax common stockholders	$ (0.21)	$ (0.20)	$ (0.41)	$ (0.39)	$ (0.69)
Shares used to compute basic and diluted net loss per share attributable to Dynavax common stockholders	182,934	161,564	170,469	125,101	82,463

(1) Includes the impact of the anti-dilution provision associated with the common stock and warrants issued to Symphony Capital Partners, L.P. and Symphony Strategic Partners, LLC (collectively, Symphony) and the change in fair value of the Symphony-related long-term contingent and warrant liabilities for the year ended December 31, 2010. See Note 8 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2012.

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	As of June 30, 2013 (Unaudited)
	(In thousands)
Consolidated Balance Sheet Data:	
Cash, cash equivalents and marketable securities	$ 89,161
Working capital	$ 77,521
Total assets	$ 104,012
Accumulated deficit	$ (473,480)
Total stockholders equity	$ 84,659

Preliminary Third Quarter 2013 Results

We estimate that our cash, cash equivalents and marketable securities were approximately $76 million as of September 30, 2013. This amount is preliminary, unaudited, subject to change upon completion of our quarterly review, and may differ from what will be reflected in our consolidated financial statements as of and for the quarter ended September 30, 2013. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of September 30, 2013. Our consolidated financial statements will not be available until after this offering is complete, and consequently will not be available to you prior to investing in this offering.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned Risk Factors contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, which is incorporated by reference in this prospectus supplement and the accompanying prospectus in its entirety, together with the other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flows could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks Related to this Offering

Our ability to use our net operating loss carryforwards and certain other tax credits may be limited.

Sections 382 and 383 of the Internal Revenue Code as enacted by the Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carryforwards by a corporation that has undergone an ownership change. Similar rules may apply under state tax laws. Due to past equity issuances and changes in the ownership of our stock, we believe that our ability to use some of our net operating losses and tax credits may be limited. As a result, if we earn net taxable income, our ability to use our net operating loss carryforwards or other tax attributes to offset United States federal and state taxable income and taxes may be subject to limitations. If we experience an ownership change in connection with this offering or as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to our net operating loss carryforwards may be further limited or lost.

Management will have broad discretion as to the use of the proceeds from this offering and our concurrent Series B Preferred Stock offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and our concurrent Series B Preferred Stock offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

Our stockholders will experience substantial additional dilution upon the conversion of Series B Convertible Preferred Stock to be issued pursuant to our concurrent Series B Preferred Stock offering.

The issuance of shares of our common stock upon conversion of Series B Convertible Preferred Stock to be sold pursuant to the Series B Preferred Stock offering would be substantially dilutive to the outstanding shares of common stock. Any dilution or potential dilution may cause our stockholders to sell their shares, which would contribute to a downward movement in the stock price of our common stock.

If you purchase the common stock sold in this offering you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $ per share and our net tangible book value as of June 30, 2013, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $ per share with respect to the net tangible book value of the common stock, but excluding the effect of conversion of shares of Series B Convertible Preferred Stock to be issued in our concurrent Series B Preferred Stock offering. See the section titled Dilution in this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

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We have a significant number of stock options and unvested restricted stock units outstanding. To the extent that these options are exercised and/or the restricted stock units are vested, investors purchasing our common stock in this offering may experience further dilution. In addition, if we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock following the expiration of the lock-up agreement we entered into with the underwriters as described in the section titled Underwriting, our stockholders, including investors who purchase shares of common stock in this offering, could experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock.

Risks Related to our Business

The success of our product candidates, in particular HEPLISAV, depends on regulatory approval. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy, consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our product candidates has been approved for sale by any regulatory agency. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approvals for our most advanced product candidates. Approval processes in the United States and in other countries are uncertain, can take many years and require the expenditure of substantial resources.

For our lead product, HEPLISAV, our BLA must be approved by the FDA and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in their respective geographic area. Obtaining approval of a BLA and corresponding foreign applications is highly uncertain and we may fail to obtain approval. The BLA review process is extensive, lengthy, expensive and uncertain, and the FDA or foreign regulatory agencies may delay, limit or deny approval of our application for many reasons, including: whether the data from our clinical trials, including the Phase 3 results, or the development program is satisfactory to the FDA or foreign regulatory agency; disagreement with the number, design, size, conduct or implementation of our clinical trials or a conclusion that the data fails to meet statistical or clinical significance; acceptability of data generated at our clinical trial sites that are monitored by third party clinical research organizations; the results of an FDA or other advisory committee that may recommend against approval of our BLA or may recommend that the FDA or other agencies require, as a condition for approval, additional preclinical studies or clinical trials; and deficiencies in our manufacturing processes or facilities or those of our third party contract manufacturers and suppliers, if any. For example, in our 2013 Complete Response Letter from the FDA (the Complete Response Letter), HEPLISAV was not approvable for the proposed indication based on insufficient patient safety data for an indication in adults 18-70 years of age without further evaluation of safety. There can be no assurance that additional clinical studies will support approval. The FDA also requested additional data from our process validation program as well as clarifying information on the manufacturing controls and facilities with respect to quality assurance of commercial product. There can be no assurance that Dynavax can successfully produce the requisite data in a timely manner or that the data will be sufficient for approval.

In addition, we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by the authorities. These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted. Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after completion of the trial. The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met. The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety, efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.

Failure to receive approval or significant delay in being able to provide the safety and manufacturing information required for approval of our BLA for HEPLISAV would have a material adverse effect on our business and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product

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may restrict to whom we and our potential partners, if any, may market the product or the manner in which our product may be administered and sold, which could significantly limit the commercial opportunity for such product.

Before granting product approval, the FDA must determine that our or our third party contractor s manufacturing facilities meet current GMP requirements before we can use them in the commercial manufacture of our products. We and all of our contract manufacturers are required to comply with the applicable current GMP regulations. Manufacturers of biological products must also comply with the FDA s general biological product standards. In addition, GMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation sufficient to ensure the quality of the approved product. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as delay of approval, suspension of manufacturing, seizure of product or voluntary recall of a product.

The FDA may require more clinical trials for our product candidate than we currently expect before granting regulatory approval, if regulatory approval is granted at all. Our clinical trials may be extended which may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

Our registration and commercial timelines depend on further discussions with the FDA and corresponding foreign regulatory agencies and requirements and requests they may make for additional data or completion of additional clinical trials. Any such requirements or requests could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- potentially limit the markets for those products;
- adversely affect our ability to enter into collaborations or receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We expect to commence additional trials of HEPLISAV and other product candidates in the future. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain IRB or other regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments.

We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll participants for our clinical trials, or are delayed for a significant time in the execution of

our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

Failure by us or our CROs to conduct a clinical study to GCP standards could result in disqualification of the clinical trial from consideration in support of approval of a potential product.

In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign

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CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of participants.

The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fail to conform to acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- our inability to obtain regulatory approval to conduct a clinical trial;

lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

our inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management s time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate that

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it be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board, or DSMB, and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial. Any such delay, suspension, termination or request to repeat or redesign a trial could increase our costs and prevent or significantly delay our ability to commercialize our product candidates.

HEPLISAV and most of our earlier stage programs rely on ISS-based technology. Serious adverse event data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.

HEPLISAV incorporates our 1018 ISS compound and most of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse event data, we may be required to delay, discontinue or modify our clinical trials or our clinical trial strategy. Most of our clinical product candidates contain ISS, and if a common safety risk across therapeutic areas were identified, it may hinder our ability to enter into potential collaboration arrangements or commercialize our product candidates. If adverse event data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

We have no commercialization experience, and the time and resources to develop sales, marketing and distribution capabilities for HEPLISAV are significant. If we fail to achieve and sustain commercial success for HEPLISAV, either directly or with a partner, our business would be harmed.

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. HEPLISAV product sales are currently expected to generate a substantial portion of our future revenue, if HEPLISAV is approved. To commercialize HEPLISAV, we must either develop sales, marketing and distribution capabilities, or make arrangements with third parties to perform these services, which will require resources and time and we may not be able to enter into these arrangements on acceptable terms. If we decide to market HEPLISAV directly, we must commit significant resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. In particular, significant resources may be necessary to successfully market, sell and distribute HEPLISAV to patients with diabetes, a group recently recommended by the CDC and ACIP to receive hepatitis B vaccination. Moreover, our pricing and reimbursement strategies with respect to our initial approval plans for HEPLISAV may significantly impact our ability to achieve commercial success in this potential patient population.

Factors that may inhibit our efforts to commercialize HEPLISAV directly or indirectly with a partner if approved include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to administer our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to expand and sustain qualified manufacturing capacity to meet demand, in particular if there is a significant increase in demand due to the recommendation to vaccinate persons with diabetes if we should obtain approval to market to those patients;
- our inability to determine appropriate pricing and reimbursement strategies for HEPLISAV in the potential patient populations that may use HEPLISAV, particularly in the diabetes market; and
- possible claims against us, including enjoining sales of HEPLISAV, based on the patent rights of others; and

unanticipated delays, costs and expenses associated with manufacturing and commercialization of our products, including costs of maintaining and scaling up manufacturing capabilities and creating and sustaining an independent sales and marketing organization in various territories.

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If we, or our partners, if any, are not successful in setting our marketing, pricing and reimbursement strategy, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing HEPLISAV, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market HEPLISAV, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, certain revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control.

We rely on our facility in Düsseldorf, Germany and third parties to supply materials or perform processes necessary to manufacture our product candidates. We rely on a limited number of suppliers to produce the ISS we will require for commercialization. Additionally, we have limited experience in manufacturing our product candidates in commercial quantities.

We rely on our facility in Düsseldorf and third parties to perform the multiple processes involved in manufacturing our product candidates, including ISS, certain antigens, the combination of ISS and the antigens, and the formulation, fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development or commercialization efforts.

We have relied on a limited number of suppliers to produce ISS for clinical trials and a single supplier to produce our 1018 ISS for HEPLISAV. To date, we have manufactured only small quantities of ISS and 1018 ISS ourselves for development purposes. If we were unable to maintain our existing supplier for 1018 ISS, we would have to establish an alternate qualified manufacturing capability, which would result in significant additional operating costs and delays in developing and commercializing our product candidates, particularly HEPLISAV. We or other third parties may not be able to produce 1018 ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. The commercial manufacturing of biological products is a time-consuming and complex process, which must be performed in compliance with current GMP regulations.

In addition, we may not be able to comply with ongoing and comparable foreign regulations, and our manufacturing process may be subject to delays, disruptions or quality control/quality assurance problems. Noncompliance with these regulations or other problems with our manufacturing process may limit, delay or disrupt the commercialization of HEPLISAV and could result in significant expense. Moreover, depending on the level of market acceptance of HEPLISAV, if approved, we may not have the capacity in our existing facility to meet all of our future commercial supply needs. Our current manufacturing capacity could supply up to approximately 2 million doses of hepatitis B surface antigen annually, and our ability to expand Düsseldorf manufacturing capacity by improving utilization in our existing facility, improving upon our current production yields or using a new facility will take time to implement and could result in substantial cost. In the event that demand exceeds our current capacity plans, we may experience a shortage in supply of HEPLISAV, which could have a material adverse effect on the success of HEPLISAV. Likewise, in the event that HEPLISAV is not approved, we would have to consider other alternatives for the facility in Düsseldorf, including its sale or closure, and any such efforts would be complex, expensive, and time-consuming.

If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.

We and our third party suppliers are required to comply with applicable current GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Suppliers of key components and materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, these third parties and our

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manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

If, as a result of their inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

We may develop, seek regulatory approval for and market our product candidates outside the United States, requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may introduce certain of our product candidates, including HEPLISAV, in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States could impose substantial burdens on our resources and divert management s attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- obtaining regulatory and pricing approvals at a level sufficient to justify commercialization;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- diverse tax consequences;

the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and

regional and geopolitical risks.

We submitted HEPLISAV for marketing approval in Europe. The Complete Response Letter from the FDA and requirement to provide additional safety data may result in further consideration of our MAA in Europe and

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we may not obtain foreign regulatory approvals on a timely basis, if at all. Specifically, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications or marketing claims, we may be unable to generate significant revenues, if any.

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved therapies;
- the potential advantages of the product over existing and future treatment methods;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the price and cost-effectiveness of the product; and
- sufficient third-party reimbursement.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

We face uncertainty regarding coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors, in particular for HEPLISAV where existing products are already marketed. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and pricing and reimbursement decisions may not allow our products to compete effectively with existing or competitive products. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is uncertain. We will have to charge a price for our products that is sufficient to enable us to recover our considerable investment in product development and our operating costs. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

We are unable to predict what impact the Health Care and Education Reconciliation Act of 2010 or other reform legislation will have on our business or future prospects. The uncertainty as to the nature and scope of the implementation of any proposed reforms limits our ability to

forecast changes that may affect our business. In Europe, the success of our products, in particular HEPLISAV, will depend largely on obtaining and maintaining government reimbursement because many providers in European countries are unlikely to use medical products that are not reimbursed by their governments. Many countries in Europe have adopted legislation and increased efforts to control prices of healthcare products. We are unable to predict the impact these actions will have on our business or future prospects.

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We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed, modified or terminated. While we conduct regular reviews of the data, we are dependent on the processes and quality control efforts of our third party contractors to ensure that detailed, quality records are maintained to support the results of the clinical trials that they are conducting on our behalf. Any extension, delay, modification or termination of our clinical trials or failure to ensure adequate documentation and the quality of the results in the clinical trials could delay or otherwise adversely affect our ability to commercialize our product candidates and could have a material adverse effect on our business and operations.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates, in particular with respect to the commercialization of HEPLISAV, if approved. Failure to obtain a collaborative relationship for HEPLISAV, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this product. We also will need to enter into or maintain collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact the willingness of companies to collaborate with us;
- our contracts for collaborative arrangements are terminable at will on written notice and may otherwise expire or terminate and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we have limited control over the decisions of our partners and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delay in the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and successfully manufacture and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

our partners may not devote sufficient capital or resources towards our product candidates; and

our partners may not comply with applicable government regulatory requirements.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative

relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

The financial terms of future collaborative licensing or financing arrangements could result in dilution of our share value.

Funding from collaboration partners and other parties may in the future involve issuance of our equity securities. Because we do not currently have any such arrangements, we cannot be certain how the terms under which such shares are issued will be determined or when such determinations will be made. The current market for financing or collaborative arrangements often involves the issuance of warrants as additional consideration in establishing the purchase price of the equity securities issued. Any such issuance could result in dilution in the value of our issued and outstanding shares.

Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to prevent or treat infectious and inflammatory diseases. For example, if it is approved, HEPLISAV will compete in the United States with established hepatitis B vaccines marketed by Merck and GSK and outside the United States with vaccines from those companies and several additional established pharmaceutical companies. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. Although certain of our employees have commercialization experience, as a company we currently have limited sales, marketing and distribution capabilities. Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified personnel. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance HEPLISAV through the development stage towards commercialization, we will need to expand our organization, including adding marketing and sales capabilities or contracting with third parties to provide these capabilities for us. As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. In addition, we expect to enhance our senior management group as we prepare to become a commercial organization. Our future financial performance and our ability to commercialize HEPLISAV and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we may not be able to manage our development efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel, and our failure to accomplish any of these activities could prevent us from successfully growing our company.

If we fail to comply with the extensive requirements applicable to biopharmaceutical manufacturers and marketers under the healthcare fraud laws of the jurisdictions in which we conduct our business, we may be subject to significant liability.

Our activities, and the activities of our agents, including some contracted third parties, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. If we obtain approval

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for and commercialize a vaccine or other product, our interactions with physicians and others in a position to prescribe or purchase our products will be subject to a legal regime designed to prevent healthcare fraud and abuse. Relevant U.S. laws include:

- the Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to the government or its agents that are false or fraudulent;

- laws that require transparency regarding financial arrangements with health care professionals, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act (PPACA) and state laws; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by state health insurance programs or any third-party payer, including commercial insurers.

The Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states Attorneys General and other governmental authorities actively enforce the laws and regulations discussed above. These entities also coordinate extensively with the FDA, using legal theories that connect violations of the Federal Food, Drug and Cosmetic Act (such as off-label promotion) to the eventual submission of false claims to government healthcare programs. Prosecution of such promotion cases under the healthcare fraud laws provides the potential for private parties (qui tam relators, or whistleblowers) to initiate cases on behalf of the government and provides for significantly higher penalties upon conviction.

In the U.S., pharmaceutical and biotechnology companies have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, or submission of incorrect pricing information.

Violations of any of the laws described above or any other applicable governmental regulations and other similar foreign laws may subject us, our employees or our agents to criminal and/or civil sanctions, including fines, civil monetary penalties, exclusion from participation in government health care programs (including Medicare and Medicaid), and the restriction or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Additionally, whether or not we have complied with the law, an investigation into alleged unlawful conduct may incur significant expense, cause reputational damage, divert management time and attention, and otherwise adversely affect our business. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants, contractors, or other agents are or will be in compliance with all applicable U.S. or foreign laws.

We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to health care fraud abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.

We depend on our senior executive officers, as well as key scientific and other personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, including our Chief Executive Officer. We recently appointed Eddie Gray to succeed Dr. Dino Dina as Chief Executive Officer. We currently have no key person insurance on any of our employees.

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We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product s safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited clinical trial liability and umbrella insurance coverage for our clinical trials. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management s attention from our business and could result in significant financial liability.

We are involved in legal actions that are expensive and time consuming, and, if resolved adversely, could harm our business, financial condition, or results of operations.

Two class action complaints brought by purported stockholders and one purported stockholder derivative complaint have been brought against us. Any negative outcome from such lawsuits could result in payments of monetary damages or fines, or adversely affect our products, and accordingly our business, financial condition, or results of operations could be materially and adversely affected.

There can be no assurance that a favorable final outcome will be obtained in these cases, and defending any lawsuit is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of monetary damages or fines, or we may decide to settle lawsuits on unfavorable terms, which could adversely affect our business, financial conditions, or results of operations.

We use hazardous materials in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We believe we are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

Risks Related to our Finances and Capital Requirements

We have incurred substantial losses since inception and do not have any commercial products that generate revenue.

We have experienced significant net losses in each year since our inception. Our accumulated deficit was $473.5 million as of June 30, 2013. To date, our revenue has resulted from collaboration agreements, government and private agency grants and services and license fees from our customers, including the customers of Rhein. We anticipate that we will incur substantial additional net losses in future years as a result of our continuing investment in research and development activities and our addition of infrastructure and operations to support regulatory approval and commercialization of HEPLISAV.

We do not have any products that generate revenue. There can be no assurance whether HEPLISAV can be further developed, financed or commercialized in a timely manner without significant additional studies or

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patient data or significant expense; whether current development efforts will be sufficient to support approval of HEPLISAV; or if approved, whether the market for HEPLISAV will be sufficient for us to reach profitability. The 2013 Complete Response Letter from the FDA for HEPLISAV means that our efforts to achieve product revenues are delayed and there can be no assurance that we will be able to achieve approval or generate meaningful sales without significant additional resources. Our ability to generate revenue depends upon obtaining regulatory approvals for our product candidates, generating product sales and entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations, enter into a transaction that constitutes a change in control of the company or raise additional capital on less than favorable terms.

If we are unable to generate significant revenues or achieve profitability, we will require substantial additional capital to continue development of our product candidates and if our most advanced candidate, HEPLISAV, is approved, to commence sales and marketing activities.

To continue development of our product candidates and, if it is approved, to launch HEPLISAV, we may need significant additional funds. Addressing this need may occur through strategic alliance and licensing arrangements and/or future public or private financings. We expect to continue to spend substantial funds in connection with:

- development, manufacturing and commercialization of our product candidates, particularly HEPLISAV;
- various human clinical trials for our product candidates; and
- protection of our intellectual property.

We currently estimate that we have sufficient resources to meet our anticipated cash needs through at least the next 12 months based on cash, cash equivalents and marketable securities on hand as well as anticipated revenues and funding from existing agreements.

Sufficient additional financing through future public or private financings, strategic alliance and licensing arrangements or other financing sources may not be available on acceptable terms or at all. Additional equity financings, if completed, could result in significant dilution or otherwise adversely affect the rights of existing stockholders. If adequate funds are not available in the future, we may need to delay, reduce the scope of, or put on hold the HEPLISAV program or other development programs while we seek strategic alternatives.

Risks Related to our Intellectual Property

We rely on licenses to intellectual property from third parties. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend in part upon our license arrangements for intellectual property owned by third parties. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the use of the licensed intellectual property and the creation and ownership of new discoveries under such license agreements. In addition, these license arrangements require us to make timely payments to maintain our licenses and typically contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these agreements could allow our licensors to terminate our agreements or undertake other remedies such as converting exclusive to non-exclusive licenses if we are unable to cure or obtain waivers for such failures or amend such agreements on terms acceptable to us. In addition, our license agreements may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot obtain and maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology or to find other alternatives to maintaining the competitive position of our products. If such alternatives are not available to us in a timely manner or on acceptable terms, we may be unable to continue development or commercialize our product candidates. In addition, we must make timely payments

or meet diligence obligations to maintain any such licenses in effect. In the absence of a current license, we may be required to redesign our technology so it does not infringe a third party s patents, which may not be possible or could require substantial funds and time.

If third parties successfully assert that we have infringed their patents and proprietary rights or challenge our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the ownership, scope or validity of our or another party s proprietary rights, including a challenge as to the validity of our issued and pending claims. From time to time we are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors, Merck and GSK, are exclusive licensees of broad patents covering methods of production of recombinant HBsAg, a component of HEPLISAV. In addition, the Institut Pasteur also owns or has exclusive licenses to patents relating to aspects of production of recombinant HBsAg. While some of these patents have expired or will soon expire outside the United States, they remain in force in the United States. To the extent we are able to commercialize HEPLISAV in the United States while these patents remain in force, Merck, GSK or their respective licensors or the Institut Pasteur may bring claims against us.

If we or our collaborators are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against our products, for example, as may arise in the commercialization of HEPLISAV or any similar product candidate, we or our collaborator could be required to pay substantial damages or be unable to commercialize our product candidates or use our proprietary technologies without a license from such third party. A license may require the payment of substantial fees or royalties, require a grant of a cross-license to our technology or may not be available on acceptable terms, if at all. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

One of our potential competitors, Pfizer, has issued patent claims, as well as patent claims pending with the PTO and foreign patent offices, that may be asserted against our ISS products. We may need to obtain a license to one or more of these patent claims held by Pfizer by paying fees or royalties or offering rights to our own proprietary technologies to commercialize one or more of our formulations of ISS other than with respect to HEPLISAV, for which we have a license. A license for other uses may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the United States, legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

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The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the United States, where we may only be able to obtain limited patent protection.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we may not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

Risks Related to an Investment in our Common Stock

Our stock price is subject to volatility, and your investment may suffer a decline in value.

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future, to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

- progress or results of any of our clinical trials or regulatory or manufacturing efforts, in particular any announcements regarding the progress or results of our planned trials and communications from the FDA or other regulatory agencies, for example as evidenced by our stock decline of over 30% following our 2013 announcement of a Complete Response Letter from the FDA and the requirement of additional safety data;

our ability to establish and maintain collaborations for the development and commercialization of our product candidates;

our ability to raise additional capital to fund our operations;

technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;

changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;

our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;

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our ability to establish and maintain licensing agreements for intellectual property necessary for the development of our product candidates;

changes in government regulations, general economic conditions or industry announcements;

issuance of new or changed securities analysts reports or recommendations;

actual or anticipated fluctuations in our quarterly financial and operating results;

our ability to maintain continued listing on the NASDAQ markets or similar exchanges; and

the volume of trading in our common stock.

One or more of these factors could cause a substantial decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk may be particularly relevant for us because we have experienced greater than average stock price volatility. We may in the future be the target of such litigation. Securities litigation could result in substantial costs, and divert management s attention and resources, which could harm our business, operating results and financial condition.

The anti-takeover provisions of our certificate of incorporation, our bylaws, Delaware law and our share purchase rights plan may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;

limiting the persons who can call special meetings of stockholders;

prohibiting stockholder actions by written consent;

creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;

providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and

establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Our share purchase rights plan may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board of Directors. Although the rights should

not interfere with any merger or other business combination approved by the Board of Directors since the rights issued may be amended to permit such acquisition or redeemed by the Company at $0.001 per right prior to the earliest of (i) the time that a person or group has acquired beneficial ownership of 20% or more of our common stock or (ii) the final expiration date of the rights, the effect of the rights plan may deter a potential acquisition of the Company. In addition, we remain subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our Board of Directors.

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We will continue to incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.

As a public company, we will continue to incur legal, accounting and other expenses associated with reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as well as new rules implemented by the Securities and Exchange Commission and the NASDAQ Stock Market LLC. We may need to continue to implement additional financial and accounting systems, procedures and controls to accommodate changes in our business and organization and to comply with new reporting requirements. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent registered public accounting firm is unable to issue an unqualified attestation as to the effectiveness of our internal control over financial reporting as of the end of our fiscal year, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

Future sales of our common stock or the perception that such sales may occur in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of June 30, 2013, we had 182,987,918 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 of the Securities Act of 1933, as amended.

In addition, we have filed shelf registration statements on Form S-3 under the Securities Act of 1933, as amended, to register securities that we may choose to issue in the future and on Form S-8 to register the shares of our common stock reserved for issuance under our stock option plans.

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FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the progress, timing and results of preclinical and clinical trials and research and development efforts involving our product candidates or the product candidates of our licensees;
- the submission of applications for and receipt of regulatory clearances and approvals;
- our product development efforts;
- our ability to commercialize our product candidates;
- the timing and introduction of our products;
- our business strategy and our expectations with respect to the implementation of our business strategy;
- our expectations with respect to the potential therapeutic and commercial value of our product candidates;
- the benefits we expect to derive from relationships with our collaborators, including potential milestone and other contingent payments and royalties;
- our expectations with respect to our intellectual property position;
- our plans to transition to a commercial operation;
- our expected capabilities;
- the effect of GAAP accounting pronouncements;
- our beliefs with respect to strengthening our senior leadership team and helping maximize long-term shareholder value;

Mr. Gray s continued role as our Chief Executive Officer and a member of our board of directors;

uncertainty regarding our future operating results and our profitability;

the successful completion of our concurrent Series B Preferred Stock offering;

the use of proceeds from this offering; and

our estimates regarding our cash, cash equivalents and marketable securities as of September 30, 2013, our capital requirements and our need for additional financing.

In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipa believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. These statements re our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading Risk Factors on page S-6 of this prospectus supplement and in our SEC filings. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus supplement, the accompanying prospectus, the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we have authorized for use

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in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

You should rely only on the information contained, or incorporated by reference, in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering. We and the underwriters for this offering have not authorized anyone to provide you with different information. The common stock offered under this prospectus is not being offered in any state where the offer is not permitted. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front of this prospectus supplement or the accompanying prospectus, as applicable, or that any information incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date of the document so incorporated by reference. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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USE OF PROCEEDS

The net proceeds from the sale of an aggregate of shares of common stock that we are offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. In addition, we estimate that the net proceeds we will receive from our concurrent Series B Preferred Stock offering will be approximately $, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. This offering is not contingent upon the completion of the Series B Preferred Stock offering and the Series B Preferred Stock offering is not contingent upon the completion of this offering. We cannot assure you that either or both of the offerings will be completed.

We intend to use the net proceeds from this offering and our concurrent Series B Preferred Stock offering primarily to fund development activities associated with conducting an additional Phase 3 study of HEPLISAV and seeking regulatory approval to commercialize the vaccine in the United States and Europe, and for other general corporate purposes, including working capital. We also may use a portion of the net proceeds from this offering and our concurrent Series B Preferred Stock offering to in-license, invest in or acquire businesses, technologies, product candidates or other intellectual property that we believe are complementary to our own, although we have no current plans, commitments or agreements to do so as of the date of this prospectus supplement. The amounts and timing of these expenditures will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing and progress of any partnering efforts, technological advances and the competitive environment for our product candidates. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short term, interest-bearing instruments.

DIVIDEND POLICY

To date, we have paid no cash dividends to our stockholders, and we do not intend to pay cash dividends in the foreseeable future.

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DILUTION

Our net tangible book value as of June 30, 2013 was approximately $82.2 million, or $0.45 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2013. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering, and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of shares of our common stock at the public offering price of $ per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2013 would have been approximately $ million, or $ per share, which excludes the effect of conversion of shares of Series B Convertible Preferred Stock to be issued in our concurrent Series B Preferred Stock offering. This represents an