DYNAVAX TECHNOLOGIES CORP
Form 424B5
October 24, 2013
Table of Contents

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Registration No. 333-191610

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

Series B Convertible Preferred Stock

We are offering shares of our Series B Convertible Preferred Stock (Series B Preferred Stock) (and the common stock issuable from time to time upon conversion of the Series B Preferred 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. There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or other nationally recognized trading system.

Each share of Series B Preferred Stock is convertible into shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of our Series B Preferred Stock will receive a payment equal to $0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of our common stock and *pari passu* with any distribution of proceeds to holders of our Series A Convertible Preferred Stock. Shares of Series B Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock will be required to amend the terms of the Series B Preferred Stock.

Concurrently with this offering of Series B Preferred Stock and pursuant to a separate prospectus supplement, we are offering shares of our common stock.

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

(1) See Underwriting beginning on page S-31 for a description of the compensation payable to the underwriters.

Investing in our Series B Preferred Stock involves a high degree of risk. See Risk Factors on page S-7 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 expects to deliver the shares of Series B Preferred Stock on or about October , 2013.

Sole Book-Running Manager

Cowen and Company

Co-Manager

William Blair

Prospectus Supplement dated October , 2013

Table of Contents

TABLE OF CONTENTS

Prospectus Supplement

Prospectus

Table of Contents

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 Series B Preferred 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 Series B Preferred Stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of Series B Preferred 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 Series B Preferred 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.

Table of Contents

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 Series B Preferred 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-7 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.

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

Table of Contents

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 Common Stock

Concurrently with this offering of Series B Preferred Stock, we are offering shares of our common stock, which we refer to herein as the common stock offering. The common 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 common stock offering and the common 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.

Table of Contents

The Offering

Issuer	Dynavax Technologies Corporation
Series B Preferred Stock offered by us in this offering	shares. This prospectus also relates to the offering of the shares of common stock issuable upon conversion of the Series B Preferred Stock.
Conversion	Each share of our Series B Preferred Stock is convertible into shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding.
Liquidation preference	In the event of our liquidation, dissolution, or winding up, holders of our Series B Preferred Stock will receive a payment equal to $0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of our common stock and *pari passu* with any distribution of proceeds to holders of our Series A Convertible Preferred Stock.
Voting rights	Shares of Series B Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series B Preferred Stock will be required to amend the terms of the Series B Preferred Stock.
Dividends	Shares of Series B Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors.
Common stock to be outstanding immediately after this offering	shares
Use of proceeds	We intend to use the net proceeds from this offering and our concurrent common 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-26 of this prospectus supplement.
Risk factors	Investing in our Series B Preferred Stock involves a high degree of risk. See Risk Factors on page S-7 of this prospectus supplement and the documents incorporated by reference into this prospectus supplement.
NASDAQ Capital Market symbol	DVAX. There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for

listing of the Series B Preferred Stock on any national securities exchange or other nationally recognized trading system.

Table of Contents

Concurrent common stock offering	Concurrently with this offering, we are offering shares of our common stock. The common 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 common stock offering and the common 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;
- shares of common stock issuable upon the conversion of the Series B Preferred Stock offered hereby; and
- shares of common stock being offered by us in connection with our concurrent common stock offering.

Table of Contents

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.

Table of Contents

	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.

Table of Contents

RISK FACTORS

An investment in our Series B Preferred Stock involves a high degree of risk. Before deciding whether to invest in our Series B Preferred 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 our concurrent common stock 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 common 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 common 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.

If you purchase the Series B Preferred Stock sold in this offering, and assuming its conversion into shares of our common stock, 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 Series B Preferred 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 Series B Preferred 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 the Series B Preferred 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. 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.

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, the issuance of shares of our common stock to be sold pursuant to the common stock offering would be substantially dilutive to the outstanding shares of common stock. Moreover, if we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock following the expiration of the lockup agreement we entered into with the underwriters as described in the section titled Underwriting, our stockholders, including investors who

Table of Contents

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.

There is no public market for the Series B Preferred Stock in this offering.

There is no established public trading market for the Series B Preferred Stock being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the Series B Preferred Stock will be limited.

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

Table of Contents

and results of operations. Even if approved, the labeling approved by the relevant regulatory authority for a product 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.

Table of Contents

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 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 adve