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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**T2 Biosystems, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>8071</b> (Primary Standard Industrial Classification Code Number)	<b>20-4827488</b> (I.R.S. Employer Identification No.)
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**101 Hartwell Avenue  
Lexington, Massachusetts 02421  
(781) 457-1200**

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

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**John McDonough  
President and Chief Executive Officer  
T2 Biosystems, Inc.  
101 Hartwell Avenue  
Lexington, Massachusetts 02421  
(781) 457-1200**

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

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*Copies to:*

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

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering	Amount of Registration Fee(2)
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	Price(1)	
Common Stock, \$0.001 par value per share	\$	\$

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated June 25, 2014

Shares



Common Stock

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This is an initial public offering of shares of common stock of T2 Biosystems, Inc. All of the \_\_\_\_\_ shares of common stock are being sold by us.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_. Application has been made to list our common stock on The NASDAQ Global Market under the symbol "TTOO".

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

See "Risk Factors" beginning on page 10 to read about factors you should consider before buying shares of our common stock.

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

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	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discount <sup>(1)</sup>	\$ _____	\$ _____
Proceeds, before expenses, to T2 Biosystems	\$ _____	\$ _____

(1) See "Underwriting (Conflict of Interest)" beginning on page 132 for additional information regarding underwriting compensation.

The underwriters have an option to purchase a maximum of \_\_\_\_\_ additional shares of common stock from us at the initial public offering price less the underwriting discount.

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The underwriters expect to deliver the shares against payment in New York, New York on or about \_\_\_\_\_, 2014.

**Goldman, Sachs & Co.**

**Leerink Partners**

**Morgan Stanley**

**Janney Montgomery Scott**

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Prospectus dated \_\_\_\_\_, 2014

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Until \_\_\_\_\_, 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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## PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 9 and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our" and "T2 Biosystems" refer to T2 Biosystems, Inc.

### Company Overview

We are an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics.

We have completed a pivotal clinical trial for our T2Dx diagnostic instrument, or T2Dx, and T2Candida panel, or T2Candida, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis. On May 27, 2014, we submitted a *de novo* petition to the FDA, requesting an order authorizing us to market T2Dx and T2Candida in the United States. Upon receipt of marketing authorization from the FDA, we intend to commercialize T2Dx and T2Candida and our goal is to launch these product candidates commercially in the United States in the first half of 2015. Our next two diagnostic applications are called T2Bacteria and T2HemoStat, which are focused on bacterial sepsis infections and hemostasis, respectively. We plan to initiate clinical trials in the second half of 2015 for T2Bacteria and in the first half of 2016 for T2HemoStat. We expect that existing reimbursement codes will support our sepsis and hemostasis product candidates, that we will have no need to seek new reimbursement codes, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals.

We believe our sepsis product candidates will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of pathogen detection. According to a study published in the *Journal of Clinical Microbiology* in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results, leading to the conclusion that "more-rapid identification of the causative organism would be highly desirable to facilitate targeted treatment in the critical phase of septic illness." Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results as fast as three hours, with an average time to result of 4.2 hours, rather than the two to five days typically required for blood-culture-based diagnostics, which we believe will enable physicians to make treatment decisions and administer targeted treatment to patients on an accelerated basis. We believe that T2Bacteria will also deliver actionable results within these timeframes because this diagnostic panel is designed to run on the same instrument as T2Candida. *Candida* has an average mortality rate of approximately 40%. According to a study published in *Antimicrobial Agents and Chemotherapy* in 2010, this mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. In a study published in the *American Journal of Respiratory and Critical Care Medicine* in 2009, providing targeted antifungal therapy within 24

hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately \$30,000 per patient.

## **Target Markets**

### **Sepsis**

Sepsis is a leading cause of death in the United States and the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection, with a mortality rate of approximately 30%. Sepsis is typically caused by one or more of five fungal *Candida* species or over 25 bacterial pathogens, and effective treatment of sepsis requires the early detection and identification of these specific target pathogens. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. This method has substantial diagnostic limitations that lead to a delay of up to several days in administration of targeted treatment as well as the incurrance of unnecessary hospital expense.

### **Hemostasis**

Another significant unmet clinical need which we believe can be addressed by T2MR is the diagnosis and management of impaired hemostasis, which is a potentially life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. For critical trauma patients with impaired hemostasis, diagnostic results are typically required in fewer than 30 minutes to aid clinicians in making the most effective treatment decisions. The need for rapid diagnosis is not met by current diagnostic methods, which typically involve multiple instruments and can take hours to process a patient specimen. As a result, physicians often make critical decisions for treatment of impaired hemostasis with limited or no diagnostic data.

### **Market Opportunity**

We believe our combined initial addressable market opportunity for sepsis and hemostasis is over \$3 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria and our initial hemostasis diagnostic panel is combined. Within the sepsis market in the United States, we estimate that there are approximately 6.75 million critical care and immunocompromised patients who present with symptoms and are at high risk for a bloodstream infection caused by *Candida* and would be appropriate to be tested by our T2Candida panel. These patients, along with approximately two million additional patients who receive treatment in the emergency room setting, are also highly susceptible to bacterial infections, for a total of approximately 8.75 million patients who are at high risk for bacterial-related sepsis and would be appropriate to be tested by our T2Bacteria panel. Within the hemostasis market, for trauma alone, there are over three million patients in the United States annually who present with symptoms of impaired hemostasis. These patients often require rapid and frequent hemostasis assessments to determine the presence and severity of abnormal coagulation, or blood clotting. As a result, the typical patient is tested at least three times during a hospital visit, which we estimate results in at least nine million diagnostic tests annually.

### **Our Technology Platform**

We have developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. Our proprietary platform is capable of detecting a variety of targets, including:

- molecular targets, such as DNA;
- immunodiagnostics, such as proteins; and

- a broad range of hemostasis measurements.

For molecular and immunodiagnostic targets, T2MR utilizes advances in the field of nanotechnology by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. We believe T2MR is the first technology that can rapidly and accurately detect the presence of molecular targets within samples without the need for time and labor-intensive purification or extraction of target molecules from the sample, such as that required by traditional polymerase chain reaction methods where 90% or more of the target can be lost. For hemostasis measurements, particles are not required because T2MR is highly sensitive to changes in viscosity within a blood sample, such as clot formation.

Utilizing T2MR technology, we have developed T2Dx, a bench-top instrument for sepsis and other applications, and we are developing T2Stat, a compact, fully integrated instrument for hemostasis applications. T2Dx is an easy-to-use, fully automated, bench-top instrument that is capable of running a broad range of diagnostic panel types from patient sample input to result. The initial panels designed to run on T2Dx are T2Candida and T2Bacteria, which are focused on identifying life-threatening pathogens associated with sepsis. We believe T2Stat is the first compact, fully integrated instrument capable of rapidly providing comprehensive hemostasis measurements. T2Stat will run our T2HemoStat panel, which includes a broad set of hemostasis measurements, including platelet function and clotting time.

#### **Our Strategy**

T2MR enables rapid and sensitive direct detection of a range of targets, and we believe it can be used in a variety of diagnostic applications that will improve patient outcomes and reduce healthcare costs. Our objective is to establish T2MR as a standard of care for clinical diagnostics. To achieve this objective, our strategy is to:

- seek marketing authorization from the FDA for T2Dx and T2Candida;
- drive commercial adoption of our sepsis products by demonstrating their value to physicians, laboratory directors and hospitals;
- establish a recurring, consumables-based business model;
- broaden our addressable markets in sepsis and hemostasis;
- broaden our addressable markets beyond sepsis and hemostasis; and
- drive international expansion.

#### **Risks Associated with Our Business**

Our business is subject to numerous risks, including:

- We have a limited operating history. We currently have no commercial products and we have not received marketing authorization from the FDA for any product.
- Marketing authorization from the FDA and regulatory approval by foreign regulatory authorities for T2Dx, T2Candida and our other diagnostic product candidates will take time and require significant research, development and clinical study expenditures, and ultimately may not be received.
- Commercialization of T2Dx, T2Candida and our other diagnostic product candidates following marketing authorization from the FDA is the key element of our strategy. If we fail to successfully commercialize T2Dx, T2Candida or such other products, whether as a result of an inability to convince hospitals and third-party payors that our product candidates will provide equal or superior diagnostic information on a more rapid basis and improve patient outcomes, or for other reasons, we may never receive a return on the significant

investments in sales and marketing, regulatory, manufacturing and quality assurance we have made, and further investments we intend to make.

- We have incurred losses since we were formed and expect to incur losses for the foreseeable future. Our accumulated deficit as of March 31, 2014 was \$98.1 million and we incurred net losses of \$20.6 million and \$6.9 million for the year ended December 31, 2013 and the three months ended March 31, 2014, respectively. We cannot be certain that we will achieve or sustain profitability or be able to raise additional capital to fund operations.
- The *in vitro* diagnostics market is highly competitive, with the involvement of more established, better-capitalized commercial companies. If we fail to compete effectively, our ability to achieve profitability will be compromised.
- If we are unable to protect our intellectual property, our ability to compete effectively after receipt of marketing authorization from the FDA will be impaired.

#### **Our Corporate Information**

We were incorporated under the laws of the state of Delaware in 2006. Our principal executive offices are located at 101 Hartwell Avenue, Lexington, Massachusetts 02421 and our telephone number is (781) 457-1200. Our website address is [www.t2biosystems.com](http://www.t2biosystems.com). The information contained in, or accessible through, our website does not constitute a part of this prospectus.

#### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An "emerging growth company" may take advantage of exemptions from some of the reporting requirements that are otherwise applicable to public companies. These exceptions include:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.



**The Offering**

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Option to purchase additional shares	The underwriters have a 30-day option to purchase a maximum of additional shares of common stock.
Use of proceeds	We intend to use the net proceeds from this offering to commercialize our T2Dx and T2Candida product candidates if they receive marketing authorization from the FDA, to fund development of our other product candidates and for working capital and general corporate purposes. See "Use of Proceeds" beginning on page 46.
Risk factors	See "Risk Factors" beginning on page 10 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	"TTOO"
Conflict of interest	Because certain affiliates of Goldman, Sachs & Co., an underwriter of this offering, beneficially own % of our common stock as of March 31, 2014, and are together entitled to designate one member of our board of directors prior to the closing of this offering, Goldman, Sachs & Co. is deemed to have a "conflict of interest" within the meaning Rule 5121 of the Financial Industry Regulatory Authority, or FINRA. Accordingly, this offering will be made in compliance with the applicable provisions of FINRA Rule 5121. FINRA Rule 5121 prohibits Goldman, Sachs & Co. from making sales to discretionary accounts without the prior written approval of the account holder and requires that a "qualified independent underwriter," as defined in FINRA Rule 5121, participate in the preparation of the registration statement and exercise its usual standards of due diligence with respect thereto. Morgan Stanley & Co. LLC has agreed to act as "qualified independent underwriter" for this offering. See "Underwriting (Conflict of Interest)".

The number of shares of our common stock to be outstanding after this offering is based on 23,678,144 shares of our common stock outstanding as of March 31, 2014, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into 21,277,722 shares of our common stock upon the closing of this offering and the issuance of \_\_\_\_\_ shares of our common stock as a result of the net exercise of all outstanding warrants, which will occur upon the closing of this offering, and excludes:

- 3,880,504 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2014, at a weighted-average exercise price of \$1.51 per share; and
- shares of our common stock reserved for future issuance under our 2014 Incentive Award Plan which will become effective on the day prior to the public trading date of our common stock, as well as shares of our common stock that become available pursuant to provisions in our 2014 Incentive Award Plan that automatically increase the share reserve under the 2014 Incentive Award Plan on January 1 of each calendar year as more fully described in "Executive and Director Compensation—2014 Incentive Award Plan".

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our preferred stock into 21,277,722 shares of our common stock, which will occur upon the closing of this offering;
- the issuance of \_\_\_\_\_ shares of our common stock as a result of the net exercise of all outstanding warrants, which will occur upon the closing of this offering, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise of outstanding stock options after March 31, 2014;
- the filing of our restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur upon the closing of this offering; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

### Summary Financial Data

The following tables set forth, for the periods and as of the dates indicated, our summary financial data. The statement of operations data for the years ended December 31, 2012 and 2013 are derived from our audited financial statements appearing elsewhere in this prospectus. The balance sheet data as of March 31, 2014 and the statement of operations data for the three months ended March 31, 2013 and 2014 and the statement of operations data for the period from our inception (April 27, 2006) to March 31, 2014 have been derived from our unaudited financial statements included elsewhere in this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of such financial data. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the captions "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". Our historical results are not necessarily indicative of our future results, and our operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other interim periods or any future year or period.

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013	2014	
(in thousands, except share and per share data)					
<b>Statement of Operations Data:</b>					
Research and grant revenue	\$ 19	\$ 266	\$ —	\$ —	\$ 3,085
Operating expenses:					
Research and development	11,727	14,936	3,561	5,065	59,388
Selling, general and administrative	2,945	5,022	1,039	1,842	22,552
Total operating expenses	14,672	19,958	4,600	6,907	81,940
Interest expense, net	(154)	(403)	(105)	(86)	(937)
Other income (expense), net	352	(515)	125	73	611
Net loss	(14,455)	(20,610)	(4,580)	(6,920)	(79,181)
Accretion of redeemable convertible preferred stock to redemption value	(4,412)	(6,908)	(1,176)	(1,906)	(21,307)
Net loss applicable to common stockholders	\$ (18,867)	\$ (27,518)	\$ (5,756)	\$ (8,826)	\$ (100,488)
Net loss per share applicable to common stockholders – basic and diluted <sup>(1)</sup>	\$ (8.15)	\$ (11.60)	\$ (2.45)	\$ (3.68)	\$ (58.62)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders – basic and diluted <sup>(1)</sup>	2,314,832	2,372,542	2,346,601	2,400,422	1,714,171

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013	2014	2014
	(in thousands, except share and per share data)				
Pro forma net loss per share applicable to common stockholders – basic and diluted (unaudited) <sup>(1)</sup>	\$	\$	\$	\$	
Pro forma weighted-average number of common shares used in computing net loss per share applicable to common stockholders – basic and diluted (unaudited) <sup>(1)</sup>					

- (1) See Note 2 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share attributable to common stockholders.

The following table presents our summary balance sheet data as of March 31, 2014:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 21,277,722 share of common stock, which will occur automatically upon the closing of this offering, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the issuance of \_\_\_\_\_ shares of common stock upon the net exercise of all outstanding warrants, which will occur upon the closing of this offering, and the resulting reclassification of the related liability for warrants to purchase redeemable securities to additional paid-in capital; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

	<b>As of March 31, 2014</b>		
	<b>Actual</b>	<b>Pro forma</b>	<b>Pro forma as adjusted</b>
	<b>(in thousands)</b>		
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 23,698		
Total assets	25,832		
Current liabilities	5,201		
Notes payable, net of current portion	2,855		
Warrants to purchase redeemable securities	1,152		
Total stockholders' deficit	(98,130)		

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total stockholders' (deficit) equity by \$ \_\_\_\_\_ million assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets and total stockholders' deficit by approximately \$ \_\_\_\_\_ million. The pro forma and pro forma as adjusted information discussed above is illustrative only and will change depending on the actual initial public offering price and other terms of our initial public offering determined at pricing.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### **Risks Related to our Business and Strategy**

***We are a development-stage company and have incurred significant losses since inception and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.***

We have incurred significant losses since inception through March 31, 2014 and expect to incur losses in the future. Our accumulated deficit as of March 31, 2014 was \$98.1 million and we incurred net losses of \$20.6 million and \$6.9 million for the year-ended December 31, 2013 and the three months ended March 31, 2014, respectively. We expect that our losses will continue for at least the next several years as we will be required to invest significant additional funds toward development and commercialization of our technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with establishing a dedicated sales force and other marketing efforts for any product candidates that receive marketing authorization from the FDA or regulatory clearance and the increased administrative costs associated with being a public company. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including our ability to achieve marketing authorization from the FDA or regulatory clearance for any product candidates, the market acceptance of our product candidates, future product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or sustain profitability.

***Our product candidates have not obtained marketing authorization from the FDA or regulatory clearance in any jurisdiction and they may never obtain such marketing authorization from the FDA or regulatory clearance.***

Our success depends on our ability to obtain marketing authorization from the FDA or regulatory clearance of T2Dx, T2Candida and other product candidates in our pipeline. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected. Our future product candidates may not be sufficiently sensitive or specific to obtain, or may prove to have other characteristics that preclude our obtaining, marketing authorization from the FDA or regulatory clearance. The process of obtaining regulatory clearance is expensive, and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of our product candidates. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the clearance of, or receipt of marketing authorization from the FDA for, a product candidate or rejection of a regulatory application altogether. The FDA has substantial discretion in the *de novo* review and clearance processes and may refuse to accept any application or may decide that our data are insufficient for clearance and require additional pre-clinical, clinical or other studies. In addition, varying

interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing authorization from the FDA or regulatory clearance of a product candidate. Any marketing authorization from the FDA or regulatory clearance we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable.

***If T2MR, our T2Dx and T2Candida product candidates or any of our other product candidates fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our growth prospects, operating results and financial condition may be harmed.***

Commercialization of T2MR, our T2Dx and T2Candida product candidates and any of our other product candidates in the United States and other jurisdictions in which we intend to pursue marketing authorization is a key element of our strategy. If we are not successful in conveying to hospitals and third-party payors that our product candidates provide equivalent or superior diagnostic information in a shorter period of time compared to existing technologies, or that these product candidates improve patient outcomes or decrease healthcare costs, we may experience reluctance, or refusal, on the part of hospitals to order, and third-party payors to pay for performing a test in which our product is utilized. For example, the T2Candida panel is likely to be labeled for the presumptive diagnosis of *Candida* infection and will require use in conjunction with other diagnostic procedures such as microbiological culture if it is authorized for marketing, meaning that our technology will complement the current standard of care, rather than serve as a replacement for the current standard of care.

These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that our technologies are appropriate options for diagnosing sepsis and impaired hemostasis, may be superior to available tests and may be more cost-effective than alternative technologies. Furthermore, we may encounter significant difficulty in gaining inclusion in sepsis and hemostasis treatment guidelines, gaining broad market acceptance by healthcare providers, third-party payors and patients using T2MR and our related product candidates. Furthermore, healthcare providers may have difficulty in maintaining adequate reimbursement for sepsis treatment, which may negatively impact adoption of our product candidates.

If we fail to successfully commercialize our product candidates, we may never receive a return on the significant investments in product development, sales and marketing, regulatory, manufacturing and quality assurance we have made and further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments.

***We have no experience in marketing and selling our product candidates, and if we are unable to successfully commercialize our products, our business may be adversely affected.***

We have no experience marketing and selling our product candidates. Upon receipt of marketing authorization from the FDA for our product candidates, we plan to sell through a direct sales force in the United States. Outside of the United States, we expect to sell our product candidates through distribution partners.

Our future sales of diagnostic products will depend in large part on our ability to successfully establish a product sales force in the United States. Because we have no experience in marketing and selling our product candidates in the diagnostics market, our ability to forecast demand, the infrastructure required to support such demand and the sales cycle of our potential customers is unproven. If we do not build an efficient and effective sales force targeting this market, our business and operating results may be adversely affected.

Moreover, there is no guarantee that we will be successful in attracting or retaining desirable distribution partners for markets outside the United States or that we will be able to enter into such

arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our product candidates effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize international sales and growth.

***Our sales cycle will be lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.***

Our sales process will involve numerous interactions with multiple individuals within an organization and will often include in-depth analysis by potential customers of our product candidates, performance of proof-of-principle studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our potential customers, the time from initial contact with a customer to our receipt of a purchase order will vary significantly and could be up to 12 months or longer. Given the length and uncertainty of our anticipated sales cycle, we likely will experience fluctuations in our product sales on a period-to-period basis. Expected revenue streams are highly dependent on hospitals' adoption of our consumables-based business model, and we cannot assure you that our potential hospital clients will follow a consistent purchasing pattern. Moreover, it is difficult for us to forecast our revenue as it is dependent upon our ability to convince the medical community of the clinical utility and economic benefits of our product candidates and their potential advantages over existing diagnostic tests, the willingness of hospitals to utilize our product candidates and the cost of our product candidates to hospitals.

***We may not be able to gain the support of leading hospitals and key thought leaders, or to publish the results of our clinical trials in peer-reviewed journals, which may make it difficult to establish T2MR as a standard of care and may limit our revenue growth and ability to achieve profitability.***

Our strategy includes developing relationships with leading hospitals and key thought leaders in the industry. If these hospitals and key thought leaders determine that T2MR and related product candidates are not clinically effective or that alternative technologies are more effective, or if we encounter difficulty promoting adoption or establishing T2MR as a standard of care, our revenue growth and our ability to achieve profitability could be significantly limited.

We believe that the successful completion of our pivotal T2Dx and T2Candida clinical trial, publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of T2MR. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving T2MR sufficiently novel or worthy of publication.

***If we are unable to successfully manage our growth, our business will be harmed.***

During the past few years, we have significantly expanded our operations. We expect this expansion to continue to an even greater degree following the closing of this offering as we seek marketing authorization from the FDA or regulatory clearance and the commercial launch of our product candidates. We intend to develop a targeted sales force in connection with our commercialization efforts. Our growth has placed and will continue to place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, operating costs may escalate even faster than planned, and some of our internal systems and processes, including those relating to manufacturing our product candidates, may need to be enhanced, updated or replaced. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased



demand, we may not be able to continue to grow or we may grow at a slower pace than expected and our business could be adversely affected.

***Our future capital needs are uncertain, and we may need to raise additional funds in the future.***

We believe that our existing cash and cash equivalents, including the funds raised in this offering, will be sufficient to meet our anticipated cash requirements for at least the next 18 months. However, we may need to raise substantial additional capital to:

- expand our product candidate offerings;
- expand our sales and marketing infrastructure;
- increase our manufacturing capacity;
- fund our operations; and
- continue our research and development activities.

Our future funding requirements will depend on many factors, including:

- our ability to obtain marketing authorization from the FDA or clearance from the FDA to market our product candidates;
- market acceptance of our product candidates, if cleared;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors for procedures using our products;
- the cost and timing of marketing authorization or regulatory clearances;
- the cost of goods associated with our product candidates;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such transactions.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates or license to third parties the rights to commercialize our product candidates or technologies that we would otherwise seek to commercialize ourselves. We also may have to reduce marketing, customer support or other resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

***Our future success is dependent upon our ability to create and expand a customer base for our product candidates in large hospitals.***

We anticipate marketing our initial product candidates, if they receive marketing authorization from the FDA, to the approximately 450 leading hospitals in the United States in which the patients highest at risk of suffering from sepsis are concentrated. We may not be successful in promoting adoption of our technologies in those hospitals, which would make it difficult for us to achieve broader market acceptance of our product candidates.

***We depend on a sole supplier for our particles and any interruption in our relationship with this party may adversely affect our business.***

Particles used in some of our product candidates are purchased from a sole source, GE Healthcare Bio-Sciences Corp., or GE Healthcare. If this supplier were to go out of business, discontinue manufacturing the particles we use or otherwise become unable to meet its supply commitments, the process of securing an alternate source could be delayed. Additionally, there can be no assurance that replacement particles will be available or will meet our quality control and performance requirements within an acceptable time. While we may be able to modify our product candidates to utilize a new source of particles, we would need to secure marketing authorization from the FDA for the modified product, and it could take considerable time and expense to perform the requisite tasks prior to petition for *de novo* review.

***If we are unable to recruit, train and retain key personnel, we may not achieve our goals.***

Our future success depends on our ability to recruit, train, retain and motivate key personnel, including our senior management, research and development, science and engineering, manufacturing and sales and marketing personnel. In particular, we are highly dependent on the management and business expertise of John McDonough, our President and Chief Executive Officer. We do not maintain fixed-term employment contracts or key man life insurance with any of our employees. Competition for qualified personnel is intense, particularly in the Boston, Massachusetts area. Our growth depends, in particular, on attracting, retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand our systems at a technical level. In addition, we may need additional employees at our manufacturing facilities to meet demand for our products as we scale up our sales and marketing operations. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, train, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

***If our diagnostics do not perform as expected, our operating results, reputation and business will suffer.***

Our success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in our product candidates. If our technology failed to detect the presence of *Candida* or another bacterial pathogen and a patient subsequently suffered from sepsis, or if our technology failed to detect impaired hemostasis and a patient faced adverse consequences from the misdiagnosis, then we could face claims against us or our reputation could suffer as a result of such failures. The failure of our current or planned diagnostic product candidates to perform as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors.

***The diagnostics market is highly competitive. If we fail to compete effectively, our business and operating results will suffer.***

If our product candidates are cleared or approved, we will compete with commercial diagnostics companies. We believe our principal competition will come from traditional blood culture-based diagnostic companies, including Becton Dickinson & Co. and bioMerieux, Inc., as well as companies offering post-culture species identification using both molecular and non-molecular methods, including bioMerieux, Inc., Bruker Corporation, Cepheid and Siemens AG.

Most of our expected competitors are either publicly traded, or are divisions of publicly traded companies, and have a number of competitive advantages over us, including:

- greater name and brand recognition, financial and human resources;
- established and broader product lines;
- larger sales forces and more established distribution networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale and lower-cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- impact of products on the health of the patient;
- impact of the use of products on the cost of treating patients in the hospital;
- cost of capital equipment;
- reputation among physicians, hospitals and other healthcare providers;
- innovation in product offerings;
- flexibility and ease-of-use;
- speed, accuracy and reproducibility of results; and
- ability to implement a consumables-based model for panels.

We believe that additional competitive factors specific to the diagnostics market include:

- breadth of clinical decisions that can be influenced by information generated by diagnostic tests;
- volume, quality and strength of clinical and analytical validation data;
- availability of adequate reimbursement for testing services and procedures for healthcare providers using our products; and
- economic benefit accrued to hospitals based on the total cost to treat a patient for a health condition.

We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our product candidates. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

***Undetected errors or defects in our product candidates could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.***

Our product candidates may contain undetected errors or defects. Disruptions or other performance problems with our product candidates may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our product candidates could harm our business and operating results.

The sale and use of product candidates or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our product candidates contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

***We may not be able to develop new product candidates or enhance the capabilities of our systems to keep pace with our industry's rapidly changing technology and customer requirements, which could have a material adverse impact on our revenue, results of operations and business.***

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our existing product candidates. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. Existing markets for our intended diagnostic product candidates are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings, our revenue, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face strong competition in the future as expected competitors develop new or improved products and as new companies enter the market with new technologies.

We are developing additional product candidates that we intend to be used with T2Dx, including T2Bacteria for detection of certain strains of sepsis-causing bacteria. We are also

developing T2Stat, to be used with our developmental T2HemoStat panel, which is designed to detect impaired hemostasis. We may have problems applying our technologies to these other areas and our new applications may not be as effective in detection as our initial applications. Any failure or delay in creating a customer base or launching new applications may compromise our ability to achieve our growth objectives.

***We currently develop, manufacture and test our product candidates and some of their components in two facilities. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.***

We currently develop our diagnostic product candidates exclusively in a facility in Lexington, Massachusetts and manufacture and test some components of our product candidates at a facility in Wilmington, Massachusetts. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if our business is disrupted for any other reason, we may not be able to develop our product candidates or test our product candidates as promptly as our potential customers expect, or possibly not at all.

The manufacture of components of our product candidates at our Wilmington facility involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

Currently, we maintain insurance coverage totaling \$9.9 million against damage to our property and equipment, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

***We may be adversely affected by fluctuations in demand for, and prices of, rare earth materials.***

T2MR relies, in part, on rare earth materials and products. For example, T2Dx utilizes magnets which are extracted from the earth. Although there are currently multiple suppliers for these rare earth materials, changes in demand for, and the market price of, these magnets could significantly affect our ability to manufacture our T2MR-based instruments and, consequently, our profitability. Rare earth minerals and product prices may fluctuate and are affected by numerous factors beyond our control such as interest rates, exchange rates, inflation or deflation, global and regional supply and demand for rare earth minerals and products, and the political and economic conditions of countries that produce rare earth minerals and products.

***Provisions of our debt instruments may restrict our ability to pursue our business strategies.***

Our credit facilities require us, and any debt instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- convey, lease, sell, transfer, assign or otherwise dispose of assets;
- change the nature or location of our business;

- complete mergers or acquisitions;
- incur indebtedness;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock (other than dividends paid solely in common stock);
- make specified investments;
- change certain key management personnel; and
- engage in material transactions with our affiliates.

These restrictions could inhibit our ability to pursue our business strategies. If we default under our credit facilities, and such event of default was not cured or waived, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to the debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our outstanding debt instruments if some or all of these instruments are accelerated upon a default.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

***As part of our current business model, we will seek to enter into strategic relationships with third parties to develop and commercialize diagnostic products.***

We intend to enter into strategic relationships with third parties for future diagnostic products. However, there is no assurance that we will be successful in doing so. Establishing strategic relationships can be difficult and time-consuming. Discussions may not lead to agreements on favorable terms, if at all. To the extent we agree to work exclusively with a party in a given area, our opportunities to collaborate with others or develop opportunities independently could be limited. Potential collaborators or licensors may elect not to work with us based upon their assessment of our financial, regulatory or intellectual property position. Even if we establish new strategic relationships, they may never result in the successful development or commercialization of future products.

***Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.***

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;

- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

***If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our product candidates.***

If treatment guidelines for sepsis change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our product candidates. For example, current treatment recommendations for *Candida* infections, including those published by the *Infectious Diseases Society of America*, call for identical treatment for two species of *Candida*, *C. albicans* and *C. tropicalis*, and identical treatment for two other species, *C. glabrata* and *C. krusei*. Although our T2Candida test is technically capable of distinguishing among these species, we have designed it based on current treatment guidelines and therefore it does not distinguish between two species if they are subject to the same recommended treatment. Our petition to the FDA requesting an order authorizing us to market T2Dx and T2Candida in the United States is also based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable for the two species currently subject to the same recommended treatment, the clinical utility of our T2Candida test could be diminished and we could be required to seek marketing authorization from the FDA for a revised test that would distinguish between the two species.

***Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.***

As of December 31, 2013, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of \$56.0 million, which are available to offset future taxable income, if any, through 2023. Under Section 382 of the Internal Revenue Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. In addition, future changes in our stock ownership, including this or future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Internal Revenue Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

***We face risks related to handling hazardous materials and other regulations governing environmental safety.***

Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. Our activities that are subject to these regulations include, among other things, our use of hazardous materials and the generation, transportation and storage of waste. We may not be in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business.

***We expect to generate a portion of our future revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results.***

We believe that a portion of our future revenue will come from international sources as we implement and expand overseas operations. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

As we expand internationally, our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.



***Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: comply with the regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

***We depend on our information technology systems, and any failure of these systems could harm our business.***

We depend on information technology systems for significant elements of our operations, including the storage of data and retrieval of critical business information. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations. These information technology systems may support a variety of functions, including laboratory operations, test validation, quality control, customer service support, billing and reimbursement, research and development activities and general administrative activities. Our clinical trial data is currently stored on a third party's servers.

Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology

systems, failures or significant downtime of our information technology systems or those used by our third-party service providers could prevent us from conducting our general business operations. Any disruption or loss of information technology systems on which critical aspects of our operations depend could have an adverse effect on our business. Further, we store highly confidential information on our information technology systems, including information related to clinical data, product designs and plans to create new products. If our servers or the servers of the third party on which our clinical data is stored are attacked by a physical or electronic break-in, computer virus or other malicious human action, our confidential information could be stolen or destroyed.

#### **Risks Related to Government Regulation and Diagnostic Product Reimbursement**

***Approval and clearance by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.***

Before we begin to label and market our product candidates for use as clinical diagnostics in the United States, we are required to obtain clearance from the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act, approval of a *de novo* reclassification petition for our product, or approval of pre-market approval, or PMA, application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down-classification, the applicant will then receive approval to market the device. This device type can then be used as a predicate device for future 510(k) submissions. We intend to utilize the *de novo* classification procedures to seek marketing authorization for T2Dx and T2Candida. The process of obtaining regulatory clearances or approvals, or completing the *de novo* classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all.

If the FDA requires us to go through a lengthier, more rigorous examination for our product candidates than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our launch to be delayed or, in the future, our sales to decline. In addition, the FDA may determine that our product candidates require the more costly, lengthy and uncertain PMA process. For example, if the FDA disagrees with our determination that the *de novo* classification procedures are the appropriate path to obtain marketing authorizations for T2Dx and T2Candida product candidates, the FDA may require us to submit a PMA application, which is generally more costly and uncertain and can take from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain 510(k) clearances with respect to those products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective, sensitive and specific diagnostic tests, for their intended users;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval. Any delay in, or failure to receive or maintain, clearance or approval for our product candidates could prevent us from generating revenue from these product candidates and adversely affect our business operations and financial results. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our product candidates and dissuade our customers from using our product candidates, if and when they are authorized for marketing.

Obtaining FDA clearance, *de novo* down classification, or approval for diagnostics can be expensive and uncertain, and generally takes from several months to several years, and generally requires detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA clearance. Even if we were to obtain regulatory clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

Even if granted, a 510(k) clearance, *de novo* down classification, or PMA approval for any future product would likely place substantial restrictions on how our device is marketed or sold, and the FDA will continue to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation, or QSR. In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our product candidates in a cost-effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Sales of our diagnostic product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA clearance and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements, or to obtain required clearances or approvals, could impair our ability to commercialize our diagnostic product candidates outside of the United States.

***Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.***

Any modification to a device authorized for marketing that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently issued this report and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a

device. However, the practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

***If we obtain marketing authorization from the FDA, a recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

***We may rely on third parties to conduct future studies of our product candidates that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily.***

We may rely on third parties, including medical investigators, to conduct such studies. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. If applicable, our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or

terminated, and we may not be able to obtain marketing authorization from the FDA or regulatory clearance for our product candidates.

***Our future customers are highly dependent on payment from third-party payors, and inadequate coverage and reimbursement for diagnostic tests using our technology or procedures using our product candidates and the commercial success of our diagnostic product candidates would be compromised.***

Successful commercialization of our diagnostic product candidates depends, in large part, to the extent the costs of our product candidates purchased by our customers are reimbursed, either separately or through bundled payment, by third-party private and governmental payors, including Medicare, Medicaid, managed care organizations and private insurance plans. There is significant uncertainty surrounding third-party coverage and reimbursement for the use of tests that incorporate new technology, such as T2MR. In addition, our business model depends, in part, on the reimbursement amount for the treatment of sepsis remaining high.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our product candidates, if approved, generally bill various third-party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our product candidates. We currently expect that the majority of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. To the extent that our diagnostic tests will be performed in an outpatient setting, our product candidates may be eligible for separate payment, for example, under the Clinical Laboratory Fee Schedule using existing Current Procedural Terminology codes. Third-party payors may deny coverage, however, if they determine that the diagnostic tests using our products are not cost-effective compared to the use of alternative testing methods as determined by the payor, or is deemed by the third-party payor to be experimental or medically unnecessary. Even if third-party payors make coverage and reimbursement available, such reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows.

Our customers' access to adequate coverage and reimbursement for inpatient procedures using our product candidates by government and private insurance plans is central to the acceptance of our products. We cannot predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. We may be unable to sell our products, if approved, on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for testing services based on our products with payors in countries outside of the United States, and our efforts may not be successful.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and other federal and state laws applicable to our business activities. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.***

Our operations are, and will continue to be, directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws may impact, among other things, our proposed sales and marketing and education programs and require us to implement additional internal systems for tracking certain marketing expenditures and reporting them to government authorities. In addition, we may be subject to patient privacy and security regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs;
- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payor program that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established new federal crimes for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, which requires manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state or foreign 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 any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians, hospitals and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these

laws. For example, the ACA, among other things, amends the intent requirement of the federal anti-kickback statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. The ACA codified case law by amending the False Claims Act, such that violations of the anti-kickback statute are now deemed violations of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

***Healthcare policy changes, including legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations.***

The ACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, certain medical device manufacturers will have to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We expect that the excise tax will apply to some or all of our diagnostic product candidates. The ACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS, further reducing payment rates. Some commercial payors are guided by the CLFS in establishing their reimbursement rates. Clinicians may decide not to order clinical diagnostic tests if third-party payments are inadequate, and we cannot predict whether third-party payors will offer adequate reimbursement for procedures utilizing our product candidates to make them commercially attractive. To the extent that the diagnostic tests using our product candidates are performed on an outpatient basis, these or any future proposed or mandated reductions in payments under the CLFS may apply to some or all of the clinical laboratory tests that our diagnostics customers may use our technology to deliver to Medicare beneficiaries and may indirectly reduce demand for our diagnostic product candidates.

Other significant measures contained in the ACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce healthcare expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our diagnostics customers use our technology to deliver beginning in 2016, and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic product candidates. To the extent that the reimbursement amounts for sepsis decrease, it could adversely affect the market acceptance and hospital adoption of our technologies.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the



years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2014 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The full impact on our business of the ACA and the other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect our industry generally or our ability to successfully commercialize our product candidates, if approved. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our product candidates or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

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

***If we are unable to protect our intellectual property effectively, our business would be harmed.***

We rely on patent protection as well as trademark, copyright, trade secret protection and confidentiality agreements to protect the intellectual property rights related to our proprietary technologies. The strength of patents in our field involves complex legal and scientific questions. Uncertainty created by these questions means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of March 31, 2014, we owned or exclusively licensed 19 issued U.S. patents and approximately 30 pending U.S. patent applications, including provisional and non-provisional filings. We also owned or licensed approximately 59 pending and granted counterpart applications worldwide. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been found. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from

issuing from a pending patent application, at all or with claims that have a scope broad enough to provide meaningful protection from our competitors.

Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as reexamination, inter-partes review, interference, opposition, or other patent office or court proceedings. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, to be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect our business.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies. These products and technologies may not be covered by claims of issued patents owned by our company. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

***We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products.***

We are a party to a number of license agreements under which we are granted rights to intellectual property that is important to our business and we expect that we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use various proprietary technologies that are material to our business, including an exclusive license to patents and patent applications from Massachusetts General Hospital, or MGH, and non-exclusive licenses from other third parties related to materials used currently in our research and development activities, and which we intend to use in our future commercial activities. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our current products and technologies or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation.

In some cases, we do not control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications either prior to our acquisition of, or entry into a license with respect to, such patents and patent applications. With respect to the patents we license from MGH, although we have rights under our agreement to provide input into prosecution and maintenance activities, and are actively involved in such ongoing prosecution, ultimately MGH retains ultimate control over such prosecution and maintenance. We therefore cannot be certain that the same attention was given, or will continue to be given, to the drafting and prosecution of these patents and patent applications as we may have exercised if we had control over the drafting and prosecution of such patents and patent applications, or that we will agree with decisions taken by MGH in relation to ongoing prosecution activities. We also cannot be certain that drafting or prosecution of the patents and patent applications licensed to us have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Further, as MGH retains the right to enforce these patents against third-party infringement, we cannot be certain that MGH will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license with MGH. If MGH fails to properly

enforce the patents subject to our license in the event of third-party infringement, our ability to retain our competitive advantage with respect to our product candidates may be materially affected.

In addition, certain of the patents we have licensed relate to technology that was developed with U.S. government grants. Federal regulations impose certain domestic manufacturing requirements and other obligations with respect to some of our products embodying these patents.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products and technologies.

***We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, enforceability and validity of others' proprietary rights, or to defend against third-party claims of intellectual property infringement, any of which could be time-intensive and costly and may adversely impact our business or stock price.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device and diagnostics industries, including patent infringement lawsuits, interferences, oppositions and inter partes review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices. While we have not received notices of claims of infringement or misappropriation or misuse of other parties' proprietary rights in the past, we may from time to time receive such notices in the future. Some of these claims may lead to litigation. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods of use of our products and technologies. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our technologies. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets or infringement by us of third-party patents, trademarks or other rights, or challenging the validity of our patents, trademarks or other rights, will not be asserted against us.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. There has been substantial

litigation and other proceedings regarding patent and other intellectual property rights in the medical diagnostics industry. Third parties may assert that we are employing their proprietary technology without authorization. Many of our competitors have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Parties making claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products and technologies. Further, defense of such claims in litigation, regardless of merit, could result in substantial legal fees and could adversely affect the scope of our patent protection, and would be a substantial diversion of employee, management and technical personnel resources from our business. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. In the event of a successful claim of infringement against us, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could therefore incur substantial costs for licenses obtained from third parties, if such licenses were available at all, which could negatively affect our gross margins, or prevent us from commercializing our products and technologies. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products to avoid infringing third-party rights. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, enforceability or scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition. Further, if the scope of protection provided by our patents or patent applications is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products.

We cannot guarantee that we have identified all relevant third-party intellectual property rights that may be infringed by our technology, nor is there any assurance that patents will not issue in the future from currently pending applications that may be infringed by our technology or product candidates. We are aware of third parties that have issued patents and pending patent applications in the United States, Europe, Canada, and other jurisdictions in the field of magnetic resonance devices and methods for analyte detection. We currently monitor the intellectual property positions of some companies in this field that are potential competitors or are conducting research and development in areas that relate to our business, and will continue to do so as we progress the development and commercialization of our product candidates. We cannot assure you that third parties will not in the future have issued patents or other intellectual property rights that may be infringed by the practice of our technology or the commercialization of our product candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or you perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business require us to defend or indemnify these parties to the extent they

become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to pursuing patents on our technology, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and technologies and discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, in order to maintain our competitive position. We take steps to protect our intellectual property, proprietary technologies and trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, corporate partners, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Our agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

***We may be subject to damages resulting from claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of our employees' former employers, or we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could hamper our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. PTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, were enacted March 16, 2013. However, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, however there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

**If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.**

We have not yet registered certain of our trademarks, including T2Biosystems, T2Candida and T2HemoStat, in all of our potential markets, including in international markets. If we apply to register these trademarks, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

**We may not be able to protect our intellectual property rights throughout the world.**

The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to technologies relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Also, because we have not pursued patents in all countries, there exist jurisdictions where we are not protected against third parties using our proprietary technologies. Further, compulsory licensing laws or limited enforceability of patents against government agencies or contractors in certain countries may limit our remedies or reduce the value of our patents in those countries.



***We use third-party software that may be difficult to replace or cause errors or failures of our product candidates that could lead to lost customers or harm to our reputation.***

We use software licensed from third parties in our product candidates. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our product candidates until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated with our technologies and products, which could harm our business. In addition, any errors or defects in, or failures of, such third-party software could result in errors or defects in the operation of our product candidates or cause our product candidates to fail, which could harm our business and reputation and be costly to correct. Many of the licensors of the software we use in our product candidates attempt to impose limitations on their liability for such errors, defects or failures. If enforceable, such limitations would require us to bear the liability for such errors, defects or failures, which could harm our reputation and increase our operating costs.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make diagnostic products and technologies that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

## Risks Related to Our Common Stock and this Offering

**One of the underwriters has an interest in this offering beyond the customary underwriting discounts and, accordingly, this offering will be made in accordance with FINRA Rule 5121 with Morgan Stanley & Co. LLC acting as "qualified independent underwriter".**

Certain affiliates of Goldman, Sachs & Co., an underwriter of this offering, beneficially own % of our common stock as of March 31, 2014, and are together entitled to designate one member of our board of directors prior to the closing of this offering. As a result, Goldman, Sachs & Co. is deemed to have a "conflict of interest" within the meaning of FINRA Rule 5121. Accordingly, this offering will be made in compliance with the applicable provisions of FINRA Rule 5121. FINRA Rule 5121 prohibits Goldman, Sachs & Co. from making sales to discretionary accounts without the prior written approval of the account holder and requires that a "qualified independent underwriter," as defined in FINRA Rule 5121, participate in the preparation of the registration statement and exercise its usual standards of due diligence with respect thereto. Morgan Stanley & Co. LLC has agreed to act as "qualified independent underwriter" for this offering. Although the "qualified independent underwriter" has participated in the preparation of this registration statement and conducted due diligence, we cannot assure you that this will adequately address any potential conflict of interest. See "Underwriting (Conflict of Interest)".

**After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.**

Upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold shares representing approximately % of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

**If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.**

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding stock options, you will incur further dilution. Based on an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid by all

purchasers of our stock but will own only approximately        % of our common stock outstanding after this offering.

***An active trading market for our common stock may not develop.***

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we have applied to have our common stock approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all.

***The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.***

Our stock price is likely to be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- development of new technologies that may address our markets and may make our technology less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes to reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds from this offering to commercialize our T2Dx and T2Candida product candidates if they receive marketing authorization from the FDA to fund development of our other product candidates and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding \_\_\_\_\_ shares of common stock based on the number of shares outstanding as of March 31, 2014 and the conversion of our redeemable convertible preferred stock into 21,277,722 shares of common stock. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after this offering. Moreover, after this offering, holders of an aggregate of \_\_\_\_\_ shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting (Conflict of Interest)" section of this prospectus.

***We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a

supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and

document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our regulatory clearance timelines, clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without

stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates, their expected performance and impact on healthcare costs, marketing authorization from the FDA, regulatory clearance, reimbursement for our product candidates, research and development costs, timing of regulatory filings, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. These forward looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a development-stage company and our expectation to incur losses in the future;
- our ability to obtain marketing authorization from the FDA or regulatory clearance for our product candidates in the United States or any other jurisdiction;
- the market acceptance of our T2MR technology;
- our ability to timely and successfully develop and commercialize our existing and future product candidates;
- the length of our anticipated sales cycle;
- our ability to gain the support of leading hospitals and key thought leaders and publish the results of our clinical trials in peer-reviewed journals;
- our future capital needs and our need to raise additional funds;
- the performance of our diagnostics;
- our ability to successfully manage our growth;
- our ability to compete in the highly competitive diagnostics market;
- our ability to protect and enforce our intellectual property rights, including our trade secret-protected proprietary rights in T2MR; and
- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not



rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

#### **INDUSTRY AND OTHER DATA**

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified statistical, market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering will be \$ \_\_\_\_\_ million (or \$ \_\_\_\_\_ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discount and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) the net proceeds to us from this offering by \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discount and estimated offering expenses payable by us, by \$ \_\_\_\_\_ million, assuming the assumed initial public offering price stays the same.

We currently intend to use the net proceeds from this offering as follows:

- approximately \$ \_\_\_\_\_ million to \$ \_\_\_\_\_ million to fund our research and development programs, which broaden our instrument and diagnostic applications utilizing T2MR technology;
- approximately \$ \_\_\_\_\_ million to \$ \_\_\_\_\_ million to obtain marketing authorization from the FDA for, and support the commercialization of, our T2Dx and T2Candida product candidates, including the hiring of additional sales, marketing and manufacturing personnel and related support costs associated with sales, marketing and manufacturing activities; and
- the balance for other general corporate purposes, including general and administrative expenses, working capital, capital expenditures to add equipment for laboratory and manufacturing-related purposes and to support expansion of facilities, and the repayment of indebtedness.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds from this offering or the actual amounts that we will spend on the uses set forth above. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials, our ability to obtain marketing authorization from the FDA for our product candidates and other development and commercialization efforts for T2Dx and T2Candida, as well as the amount of cash used in our operations. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Silicon Valley Bank, unless Silicon Valley Bank provides prior written consent.

**CAPITALIZATION**

The following table sets forth our capitalization as of March 31, 2014:

- on an actual basis;
- on a pro forma basis to reflect the automatic conversion of all outstanding shares of our preferred stock into 21,277,722 shares of common stock upon the closing of this offering, the issuance of        shares of our common stock upon the net exercise of all outstanding warrants, which will occur upon the closing of this offering, assuming an initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the resulting reclassification of the related liability for warrants to purchase redeemable securities to additional paid-in capital; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of        shares of common stock in this offering at an assumed initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

	<u>As of March 31, 2014</u>		
	<u>Actual</u>	<u>Pro Forma</u>	<u>Pro Forma As</u>
		<u>Adjusted</u>	
		<u>(in thousands)</u>	
	\$	\$	\$
Notes payable, net of current portion	2,855		
Warrants to purchase redeemable securities	1,152		
<b>Redeemable convertible preferred stock:</b>			
Series A-1 redeemable convertible preferred stock, \$0.001 par value; 282,849 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	885		
Series A-2 redeemable convertible preferred stock, \$0.001 par value; 1,717,728 shares authorized, 1,703,959 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	7,824		
Series B redeemable convertible preferred stock, \$0.001 par value; 3,523,765 shares authorized, 3,249,877 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	15,681		
Series C redeemable convertible preferred stock, \$0.001 par value; 4,085,125 shares authorized, 4,055,125 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	19,401		

	As of March 31, 2014	
	Actual	Pro Forma As Adjusted (in thousands)
Series D redeemable convertible preferred stock, \$0.001 par value; 5,074,725 shares authorized, 5,054,945 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	27,822	
Series E redeemable convertible preferred stock, \$0.001 par value; 6,960,967 shares authorized, 6,930,967 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	43,106	
Common stock, par value \$0.001 per share; 28,254,907 shares authorized, 2,400,422 shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	2	
Preferred stock, par value \$0.001 per share; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted		
Additional paid-in capital	—	
Deficit accumulated during the development stage	(98,132)	
Total stockholders' (deficit) equity	(98,130)	
Total capitalization	\$ 20,596	\$

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of additional paid-in capital, total stockholders' (deficit) equity and total capitalization by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of additional paid in capital, total stockholders' (deficit) equity and total capitalization by \$ million.

The number of shares in the table above does not include:

- 3,880,504 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014, at a weighted-average exercise price of \$1.51 per share; or
- shares of our common stock reserved for future issuance under our incentive award plans.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of March 31, 2014, we had a net tangible book value of \$(98.1) million, or \$(40.88) per share of common stock. Our net tangible book value per share represents total tangible assets less total liabilities and redeemable convertible preferred stock, divided by the number of shares of our common stock outstanding as of March 31, 2014.

Our pro forma net tangible book value as of March 31, 2014 was \$            million, or \$            per share of our common stock. Pro forma net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of March 31, 2014, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering, assuming an initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the issuance of            shares of common stock upon the net exercise of all outstanding warrants, which will occur upon the closing of this offering and the resulting reclassification of the related liability for warrants to purchase redeemable securities to additional paid-in capital.

After giving further effect to our sale of            shares of common stock in this offering at an assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2014 would have been \$            million, or \$            per share. This amount represents an immediate increase in pro forma net tangible book value of \$            per share to our existing stockholders and an immediate dilution of \$            per share to new investors in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock. The following table illustrates this dilution:

Assumed initial public offering price per share	\$
Net tangible book value per share as of March 31, 2014	\$ (40.88)
Increase in net tangible book value per share attributable to the conversion of our preferred stock and net exercise of warrants	_____
Pro forma net tangible book value per share as of March 31, 2014	_____
Increase in pro forma net tangible book value per share attributable to this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors in this offering	\$ _____

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$            per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by \$            , and dilution in pro forma net tangible book value per share to new investors by \$            , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and

estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and decrease (increase) the dilution to new investors by \$ \_\_\_\_\_ per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discount and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be \$ \_\_\_\_\_ per share, the increase in pro forma net tangible book value per share would be \$ \_\_\_\_\_ and the dilution per share to new investors would be \$ \_\_\_\_\_ per share, in each case assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, on a pro forma as adjusted basis as described above, as of March 31, 2014, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid. The calculation below is based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discount and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders			%\$		%\$
New investors					
<b>Total</b>		<b>100%</b>		<b>100%</b>	

The foregoing tables and calculations are based on the number of shares of our common stock outstanding as of March 31, 2014, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering and the net exercise of all outstanding warrants, which will occur upon the closing of this offering, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and exclude:

- 3,880,504 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014, at a weighted-average exercise price of \$1.51 per share; and
- shares of our common stock reserved for future issuance under our incentive award plans.

To the extent any of the outstanding stock options are exercised, there will be further dilution to new investors. If all of such outstanding stock options had been exercised as of March 31, 2014, the pro forma as adjusted net tangible book value per share after this offering would have been \$ \_\_\_\_\_, and total dilution per share to new investors would have been \$ \_\_\_\_\_.

If the underwriters exercise in full their option to purchase additional shares of our common stock:

- the percentage of shares of common stock held by existing stockholders will decrease to \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to \_\_\_\_\_, or \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering.

**SELECTED FINANCIAL DATA**

The following tables set forth, for the periods and as of the dates indicated, our selected financial data. The statement of operations data for the years ended December 31, 2012 and 2013 and balance sheet data as of December 31, 2012 and 2013 are derived from our audited financial statements appearing elsewhere in this prospectus. The balance sheet data as of March 31, 2014 and the statement of operations data for the three months ended March 31, 2013 and 2014 and the statement of operations data for the period from our inception (April 27, 2006) to March 31, 2014 have been derived from our unaudited financial statements included elsewhere in this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of such financial data. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations". Our historical results are not necessarily indicative of our future results, and our operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other interim periods or any future year or period.

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013	2014	
	(in thousands, except share and per share data)				
<b>Statement of Operations Data:</b>					
Research and grant revenue	\$ 19	\$ 266	\$ —	\$ —	\$ 3,085
Operating expenses:					
Research and development	11,727	14,936	3,561	5,065	59,388
Selling, general and administrative	2,945	5,022	1,039	1,842	22,552
Total operating expenses	14,672	19,958	4,600	6,907	81,940
Interest expense, net	(154)	(403)	(105)	(86)	(937)
Other income (expense), net	352	(515)	125	73	611
Net loss	(14,455)	(20,610)	(4,580)	(6,920)	(79,181)
Accretion of redeemable convertible preferred stock to redemption value	(4,412)	(6,908)	(1,176)	(1,906)	(21,307)
Net loss applicable to common stockholders	\$ (18,867)	\$ (27,518)	\$ (5,756)	\$ (8,826)	\$ (100,488)
Net loss per share applicable to common stockholders – basic and diluted <sup>(1)</sup>	\$ (8.15)	\$ (11.60)	\$ (2.45)	\$ (3.68)	\$ (58.62)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders – basic and diluted <sup>(1)</sup>	2,314,832	2,372,542	2,346,601	2,400,422	1,714,171
Pro forma net loss per share applicable to common stockholders – basic and diluted (unaudited) <sup>(1)</sup>		\$		\$	\$
Pro forma weighted-average number of common shares used in computing net loss per share applicable to common stockholders – basic and diluted (unaudited) <sup>(1)</sup>					

(1) See Note 2 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share attributable to common stockholders.

	As of December 31,		As of
	2012	2013	March 31, 2014
<b>Balance Sheet Data:</b>	(in thousands)		
Cash and cash equivalents	\$ 9,709	\$ 30,198	\$ 23,698
Total assets	11,431	31,885	25,832
Notes payable, net of current portion	5,058	3,299	2,855
Current liabilities	2,129	4,046	5,201
Warrants to purchase redeemable securities	695	1,225	1,152
Redeemable convertible preferred stock	66,137	112,813	114,719
Total stockholders' deficit	(62,658)	(89,543)	(98,130)



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need where existing therapies could be more effective with improved diagnostics. We have completed a pivotal clinical trial for T2Dx and T2Candida and, on May 27, 2014, we submitted a *de novo* petition to the U.S. Food and Drug Administration, or the FDA, requesting an order authorizing us to market T2Dx and T2Candida in the United States. Our goal is to launch T2Dx and T2Candida commercially in the United States in the first half of 2015. In addition, we expect to initiate clinical trials for our bacterial sepsis and hemostasis product candidates in the second half of 2015 and the first half of 2016, respectively, and are targeting to commercialize these product candidates in 2017. We believe our combined initial addressable market opportunity for sepsis and hemostasis is over \$3 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria and our initial hemostasis diagnostic panel is combined.

Since our inception in 2006, we have devoted substantially all of our resources to the development of T2MR and applications of T2MR. We do not have marketing authorization or regulatory approval in any jurisdiction to sell any products and have not generated any revenue from product sales. Since our inception through March 31, 2014, we have raised an aggregate of \$101.9 million to fund our operations, of which \$93.4 million was from the sale of preferred stock, and \$8.3 million and \$0.2 million were from the issuance of debt and common stock, respectively.

We have never been profitable and have incurred net losses in each year since inception. Our net losses, for the period from April 27, 2006 (inception) to March 31, 2014, totaled \$98.1 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We do not expect to generate revenue from product sales unless and until we obtain marketing authorization from the FDA for T2Dx and T2Candida. If we obtain marketing authorization for T2Dx and T2Candida, or any of our other products, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other products and maintain, expand and protect our intellectual property portfolio. Accordingly, we will seek to fund our operations through public or private equity or debt.

financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize our product candidates.

## **Financial Overview**

### **Revenue**

To date, we have generated revenue primarily from research and development agreements and government grants and have not generated any revenue from the sale of products. Revenue earned from activities performed pursuant to research and development agreements and grants is reported as revenue using the proportional performance method as the work is completed, and the related costs are expensed as incurred as research and development expense.

Our product candidate revenue will be derived from the sale of our instruments and related consumable diagnostic tests. In the majority of cases, we expect to place instruments at hospitals at minimal or no direct cost to customers in exchange for longer-term agreements and minimum commitments for the purchase of our consumable diagnostic tests. Under this business model, we believe we will recover the cost of placing our instruments at hospitals through the incremental price we charge for our consumable diagnostic tests. Our consumable diagnostic tests can only be used with our instruments. Accordingly, as the installed base of our instruments grows, we expect the following to occur:

- recurring revenue from our consumable diagnostic tests will increase and become subject to less period-to-period fluctuation;
- consumable revenue will become an increasingly predictable and important contributor to our total revenue; and
- we will gain economies of scale through the growth in our sales, resulting in improving gross margins and operating margins.

Revenue from consumables is expected to be based on the volume of tests sold and the price of each consumable unit. In the event that revenue arrangements contain multiple deliverables, revenue will be recognized upon the delivery of each of the elements once the appropriate revenue criteria is met.

We plan to continue to expand our capacity to support our growth, which will result in higher cost of revenue in absolute dollars. However, we expect cost of revenue, as a percentage of revenue, to decline as revenue grows.

### **Research and development expenses**

Our research and development expenses consist primarily of costs incurred for development of our technology and product candidates, technology improvements and enhancements, clinical trials to evaluate the clinical utility of our product candidates, and laboratory development and expansion, and include salaries and benefits, including stock-based compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services. We expense all research and development costs as incurred.

We have incurred a total of \$59.4 million in research and development expenses from inception through March 31, 2014, with a majority of the expenses being spent on the development of T2MR, and applications of T2MR, and the remainder being spent on clinical trials and research and development of additional applications using T2MR. We expect that our overall research and development expenses will continue to increase in absolute dollars. We have committed, and

expect to commit, significant resources developing additional product candidates, improving product performance and reliability, conducting ongoing and new clinical trials and expanding our laboratory capabilities.

#### **Selling, general and administrative expenses**

Selling, general and administrative expenses consist primarily of costs for our sales and marketing, finance, human resources, business development and general management functions, as well as professional services, such as legal, consulting and accounting services. We expect selling, general and administrative expenses to increase in future periods as we commercialize product candidates that receive marketing authorization or regulatory clearance and as our needs for sales, marketing and administrative personnel grow. Other selling, general and administrative expenses include facility-related costs, fees and expenses associated with obtaining and maintaining patents, clinical and economic studies and publications, marketing expenses, and travel expenses. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with being a public company. We expense all selling, general and administrative expenses as incurred.

#### **Interest expense, net**

Interest expense, net consists primarily of interest expense on our notes payable and the amortization of deferred financing costs, partially offset by interest earned on our cash and cash equivalents.

#### **Other income (expense), net**

Other income and expense consists primarily of the gain or loss associated with the change in the fair value of our preferred stock warrant liability.

#### **Results of Operations for the Three Months Ended March 31, 2013 and March 31, 2014**

	Three Months Ended March 31,		Change
	2013	2014	
	(in thousands)		
Research and grant revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	3,561	5,065	1,504
Selling, general and administrative	1,039	1,842	803
Total operating expenses	4,600	6,907	2,307
Loss from operations	(4,600)	(6,907)	(2,307)
Interest expense, net	(105)	(86)	19
Other income (expense), net	125	73	(52)
Net loss	<u>\$ (4,580)</u>	<u>\$ (6,920)</u>	<u>\$ (2,340)</u>

#### **Research and development expenses**

Research and development expenses were \$5.1 million for the three months ended March 31, 2014, compared to \$3.6 million for the three months ended March 31, 2013, an increase of \$1.5 million. The increase was primarily due to increased travel and site expenses of \$0.8 million

related to the pivotal clinical trial for T2Dx and T2Candida, increased payroll and payroll related expense of \$0.4 million, including stock compensation, as we increased full-time and temporary headcount, increased lab expenses by \$0.1 million and increased consulting expenses by \$0.1 million to support product development.

#### **Selling, general and administrative expenses**

Selling, general and administrative expenses were \$1.8 million for the three months ended March 31, 2014, compared to \$1.0 million for the three months ended March 31, 2013. The increase of \$0.8 million was due primarily to increased payroll and related expenses of \$0.5 million, including stock compensation expense, as we hired new sales and administrative employees, increased marketing programs by \$0.1 million, including trade shows, website redesign and collateral, and increased consulting related expenses of \$0.1 million.

#### **Interest expense, net**

Interest expense, net decreased for the three months ended March 31, 2014, compared to the three months ended March 31, 2013, due to lower borrowing levels on our notes payable.

#### **Other income (expenses), net**

Other income (expense), net, for the three months ended March 31, 2014, declined when compared with the three months ended March 31, 2013, due to a decrease in income from the revaluation of the fair value of the liability for warrants to purchase redeemable securities.

#### **Results of Operations for the Years Ended December 31, 2012 and 2013**

	<b>Year Ended December 31,</b>		<b>Change</b>
	<b>2012</b>	<b>2013</b>	
	(in thousands)		
Research and grant revenue	\$ 19	\$ 266	\$ 247
Operating expenses:			
Research and development	11,727	14,936	3,209
Selling, general and administrative	2,945	5,022	2,077
Total operating expenses	14,672	19,958	5,286
Loss from operations	(14,653)	(19,692)	(5,039)
Interest expense, net	(154)	(403)	(249)
Other income (expense), net	352	(515)	(867)
Net loss	<u>\$ (14,455)</u>	<u>\$ (20,610)</u>	<u>\$ (6,155)</u>

#### **Revenue**

We recorded \$0.3 million of research and grant revenue for the year ended December 31, 2013, which primarily consisted of revenue related to feasibility studies and co-development efforts with three companies. For the year ended December 31, 2012, we recorded \$19,000 in research and grant revenue, which primarily consisted of work completed under a third-party development agreement, offset by the fair value of warrants issued in conjunction with the agreement, which were recorded as a reduction to revenue.

**Research and development expenses**

Research and development expenses were \$14.9 million for the year ended December 31, 2013, compared to \$11.7 million for the year ended December 31, 2012, an increase of \$3.2 million. The increase was primarily due to increased payroll and payroll related expense of \$1.1 million, including stock compensation, as we hired new employees, increased lab expenses to support product development, increased travel and site expenses of \$2.1 million related to the pivotal clinical trial for T2Dx and T2Candida.

**Selling, general and administrative expenses**

Selling, general and administrative expenses were \$5.0 million for the year ended December 31, 2013, compared to \$2.9 million for the year ended December 31, 2012. The increase of \$2.1 million was due primarily to increased payroll and related expenses of \$0.9 million, including stock compensation expense, as we hired new administrative employees, increased marketing programs of \$0.5 million, including tradeshows and collateral, increased legal expenses of \$0.2 million related to corporate and intellectual property matters, and increased consulting related expenses of \$0.2 million.

**Interest expense, net**

Interest expense, net, increased for the year ended December 31, 2013, compared to the year ended December 31, 2012, due to higher borrowing levels in 2013 under our credit facility with Silicon Valley Bank.

**Other income (expense), net**

Other income (expense), net, for the years ended December 31, 2012 and 2013, was due to revaluation of the fair value of the liability for warrants to purchase redeemable securities.

**Liquidity and Capital Resources**

We have incurred losses and cumulative negative cash flows from operations since our inception in April 2006, and as of March 31, 2014, we had a deficit accumulated in the development stage of \$98.1 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally from the issuance of preferred stock, common stock and notes payable. Since our inception through March 31, 2014, we have raised an aggregate of \$101.9 million to fund our operations, of which \$93.4 million was from the sale of preferred stock, \$8.3 million was from our debt instruments and \$0.2 million was from the issuance of common stock. As of March 31, 2014, we had cash and cash equivalents of \$23.7 million. Currently, our funds are primarily held in money market funds consisting of U.S. government-backed securities.

**Indebtedness**

On May 9, 2011, we entered into a promissory note with Massachusetts Development Finance Company to borrow up to \$1.7 million for the purchase of laboratory equipment and office equipment. The amounts borrowed are collateralized by the associated equipment and bear interest

at a fixed annual rate of 6.5%. Pursuant to the note, we are required to meet a liquidity covenant whereby we must maintain a cash balance of \$0.3 million in cash and marketable securities. We paid interest only on the borrowings through December 2013 and will continue to make equal monthly payments of principal and interest through the maturity date of May 2018. In connection with the note, we issued a warrant that is exercisable for shares of our series C preferred stock.

On June 30, 2007, we entered into a loan and security agreement with Silicon Valley Bank, as amended on June 26, 2009 and June 25, 2012. Our outstanding borrowings as of March 31, 2014 relate to the June 25, 2012 amendment, which allowed us to borrow up to \$4.5 million through December 31, 2012. The amounts borrowed are collateralized by our assets other than intellectual property and bear interest at the greater of a floating rate based on the prime rate or a fixed rate of 6.25%. The debt can be prepaid at our option, and is subject to a prepayment premium of 2% if it is repaid prior to the first anniversary of the borrowing date, and 1% if it is repaid prior to the second anniversary of the borrowing date. Under the terms of the loan and security agreement, we paid interest only on the borrowings through June 30, 2013 and have made and thereafter will continue to make equal monthly payments of principal plus monthly payments of accrued interest. In connection with the loan and security agreement and related amendments, we issued warrants exercisable for shares of our series A-2 preferred stock, series B preferred stock and series D preferred stock.

In addition, the promissory note with Massachusetts Development Finance Company contains a subjective acceleration clause whereby an event of default and immediate acceleration of the borrowing under the security and loan agreement occurs if we experience a material adverse change in the business, operations or condition (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations. The lender has not exercised its right under this clause, as there have been no such events. We believe that the likelihood of the lender exercising this right is remote.

As of March 31, 2014, we had \$4.6 million outstanding under these debt instruments and were in compliance with all financial covenants.

#### ***Plan of operations and future funding requirements***

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

We believe that our existing cash and cash equivalents, including the net proceeds of this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 18 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Additionally, the process of testing our product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and revenue from potential research and development and other collaboration agreements. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds in the future, we may have to relinquish valuable rights to our technologies, future

revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant licenses to develop and market products that we would otherwise prefer to develop and market ourselves.

### Cash flows

The following is a summary of cash flows for each of the periods set forth below:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
	(in thousands)			
Net cash (used in) provided by:				
Operating activities	\$ (13,303)	\$ (18,053)	\$ (3,867)	\$ (5,791)
Investing activities	(283)	(433)	(35)	(263)
Financing activities	4,551	38,975	39,749	(446)
Net (decrease) increase in cash and cash equivalents	<u>\$ (9,035)</u>	<u>\$ 20,489</u>	<u>\$ 35,847</u>	<u>\$ (6,500)</u>

#### Net cash used in operating activities

Net cash used in operating activities was \$5.8 million for the three months ended March 31, 2014, and consisted primarily of a net loss of \$6.9 million adjusted for non-cash items including depreciation and amortization expense of \$0.1 million, stock-based compensation expense of \$0.2 million, a decrease in the fair value of warrants of \$0.1 million and a net change in operating assets and liabilities of \$0.8 million.

Net cash used in operating activities was \$3.9 million for the three months ended March 31, 2013, and consisted primarily of a net loss of \$4.6 million adjusted for non-cash items including depreciation and amortization expense of \$0.1 million, stock-based compensation expense of \$0.1 million, a decrease in the fair value of warrants of \$0.1 million and a net change in operating assets and liabilities of \$0.6 million.

Net cash used in operating activities was \$18.1 million for the year ended December 31, 2013, and consisted primarily of a net loss of \$20.6 million adjusted for non-cash items including depreciation and amortization expense of \$0.6 million, stock-based compensation expense of \$0.6 million, an increase in the fair value of warrants of \$0.5 million and a net change in operating assets and liabilities of \$0.8 million.

Net cash used in operating activities was \$13.3 million for the year ended December 31, 2012, and consisted primarily of a net loss of \$14.5 million adjusted for non-cash items including depreciation and amortization expense of \$0.6 million, stock-based compensation expense of \$0.4 million, decrease in the fair value of warrants of \$0.1 million and a net change in operating assets and liabilities of \$0.2 million.

#### Net cash used in investing activities

Net cash used in investing activities was \$0.3 million for the three months ended March 31, 2014, and consisted of \$0.3 million of purchases of laboratory equipment and computer software.

Net cash used in investing activities was \$35,000 for the three months ended March 31, 2013, and consisted of \$115,000 of purchase of laboratory equipment, partially offset by \$80,000 of proceeds from restricted cash accounts related to an operating lease agreement.

Net cash used in investing activities was \$0.4 million for the year ended December 31, 2013, and consisted primarily of capital expenditures of \$0.5 million, for laboratory equipment and leasehold improvements, partially offset by a \$0.1 million of proceeds from restricted cash accounts related to an operating lease agreement.

Net cash used in investing activities was \$0.3 million for the year ended December 31, 2012, and consisted primarily of purchases of laboratory equipment.

#### **Net cash (used in) provided by financing activities**

Net cash used in financing activities was \$0.4 million for the three months ended March 31, 2014, and consisted of \$0.4 million of repayments of notes payable.

Net cash provided by financing activities was \$39.7 million for the three months ended March 31, 2013, and primarily related to the sale of 6.9 million shares of our series E preferred stock for net proceeds of \$39.8 million, partially offset by \$0.1 million of repayments of notes payable.

Net cash provided by financing activities during the year ended December 31, 2013 was primarily related to the sale of 6.9 million shares of our series E preferred stock for net proceeds of \$39.8 million, partially offset by repayments of notes payable of \$0.8 million.

Net cash provided by financing activities during the year ended December 31, 2012 was primarily related to the issuance of notes payable for net proceeds of \$4.9 million, partially offset by repayments of notes payable of \$0.4 million.

#### **Contractual Obligations and Contingent Liabilities**

The following summarizes our significant contractual obligations as of December 31, 2013:

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More than 5 Years</u>
	(in thousands)				
Operating leases <sup>(1)</sup>	\$ 1,273	\$ 649	\$ 624	\$ —	\$ —
Notes payable <sup>(2)</sup>	5,673	2,066	3,479	128	—
<b>Total obligations</b>	<b>\$ 6,946</b>	<b>\$ 2,715</b>	<b>\$ 4,103</b>	<b>\$ 128</b>	<b>\$ —</b>

- (1) Represents the leases of approximately 27,000 square feet for office, laboratory and manufacturing space in Lexington, Wilmington and Worcester, Massachusetts under noncancelable operating leases that expire in January 2016 and December 2015.
- (2) Represents our promissory note with Massachusetts Development Finance Company and our loan and security agreement with Silicon Valley Bank that currently bear interest at annual rates of 6.5% and 6.25%, respectively, and have principal repayment dates through May 2018. The balance for these debt instruments includes interest payment obligations.

#### **Net operating loss carry forwards**

We have deferred tax assets of \$30.1 million as of December 31, 2013, which have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal net operating loss, or NOL, tax



carryforwards and research and development tax credit carryforwards. As of December 31, 2013, we had federal NOL carryforwards of \$56.0 million available to reduce future taxable income, if any. These federal NOL carryforwards are available to offset future taxable income, if any, through 2023. In general, if we experience a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. We have not conducted an assessment to determine whether there may have been a Section 382 ownership change. If we experience a Section 382 ownership change in connection with this offering or as a result of future changes in our stock ownership, some of which changes are outside of our control, the tax benefits related to the NOL carryforwards may be limited or lost.

### **Critical Accounting Policies and Use of Estimates**

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

#### ***Revenue recognition***

We have generated revenue primarily from research and development agreements and government grants. The timing of cash received from our research and development agreements generally differs from when revenue is recognized. Revenue is recognized when persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. Revenue earned from activities performed pursuant to research and development agreements and grants are reported as revenue on a proportional performance basis as the work is completed, and the related costs are expensed as incurred as research and development expense.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue.

#### ***Stock-based compensation***

We issue stock-based awards to employees and non-employees, generally in the form of stock options and restricted stock. We account for our stock-based awards in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation*, or ASC 718. ASC 718 requires all

stock-based payments to employees, including grants of employee stock options and modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their grant date fair values. We account for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees*, which requires the fair value of the award to be remeasured at fair value as the award vests. We recognize the compensation cost of stock-based awards to employees and non-employees on a straight-line basis over the vesting period. See below for a detailed description of how we estimate fair value for purposes of option grants and the methodology used in measuring stock-based compensation expense. Following the consummation of this offering, stock option and restricted stock values will be determined based on the market price of our common stock.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes-Merton option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of our stock, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of our common stock and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period in which the options were granted.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. If our actual forfeiture rate is materially different from the estimate, our stock-based compensation expense could be different from what we have recorded in the current period.

We have computed the fair value of employee and non-employee stock options at date of grant using the following estimated assumptions:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
Risk-free interest rate	1.35%	1.68%	1.02%	2.04%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected volatility	64%	63%	64%	62%
Expected term (in years)	6.25 - 10	5.77 - 6.08	6.08	6.02 - 6.08

These assumptions represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use

significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

We have recognized the following compensation cost related to employee and non-employee stock option and restricted stock activity:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
	(in thousands)			
Research and development	\$ 160	\$ 169	\$ 46	\$ 56
Selling, general and administrative	243	409	76	183
Total stock-based compensation expense	<u>\$ 403</u>	<u>\$ 578</u>	<u>\$ 122</u>	<u>\$ 239</u>

#### Determination of the Fair Value of Common Stock on Grant Dates

The fair value of the common stock underlying our share-based awards was determined by our board of directors, with input from management and contemporaneous third-party valuations. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. However, the fair value of our common stock may vary significantly in the future and from the estimates previously made. As described below, the exercise price of our share-based awards was also generally determined by our board of directors based on the most recent contemporaneous third-party valuation.

Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants, or AICPA, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation Accounting and Valuation Guide*, or the Practice Aid, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock including:

- our capital structure, including the rights and preferences of our various classes of equity;
- lack of marketability of our common stock;
- our historical operating results, current business conditions and projections;
- our stage of development;
- likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company, given prevailing market conditions; and
- the market performance of comparable publicly traded companies.

In valuing our common stock, since 2011, our board of directors determined the equity value of our business using the income approach valuation method or, when applicable due to a recent offering of our redeemable convertible preferred stock, the back solve method of the option pricing model, or OPM, to determine the enterprise value. The income approach determines our enterprise value on the basis of the estimated present value of our projected future cash flows. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in our industry or similar lines of business as of each valuation date and this discount rate is adjusted to reflect the risks inherent in our cash flows. Once calculated, the results of the income approach were relied upon to determine an estimated enterprise value.

The back solve method of the OPM estimates our enterprise value by considering any prior sales of our capital stock. When considering prior sales of our equity, the valuation considers the circumstances surrounding the sale, such as the size of the equity sale, the relationship of the parties involved in the transaction, the timing of the equity sale and the rights, preferences and privileges of the capital stock sold in the transaction.

Our peer group of publicly traded companies used for determination of the discount rate and market trading multiples consists of six companies that focus primarily on providing biotechnology diagnostic solutions that are similar to our current product candidates. There are, however, significant size and risk differences between our selected peer group of guideline public companies and us.

For valuations prior to December 31, 2013, after we determined an enterprise value, we utilized the OPM to allocate the equity value to each of our classes of stock. The OPM values each equity class by creating a series of call options on our equity value, with exercise prices based on the liquidation preferences, participation rights and strike prices of derivatives. This method is generally preferred when future outcomes are difficult to predict and dissolution or liquidation is not imminent. In addition, we considered an appropriate discount adjustment to recognize the lack of marketability as a private company. The OPM uses the Black-Scholes-Merton option-pricing model to price the call option.

Because we believed there was greater clarity about potential exit scenarios, including a possible initial public offering, beginning with the December 31, 2013 valuation described below, we began using the probability weighted expected return method, or PWERM, to allocate our equity value among the various potential outcomes. Using the PWERM, the value of our common stock is estimated based upon an analysis of varying values for our common stock assuming the following possible future events for our company:

- the completion of an initial public offering;
- the completion of a sale of our company; and
- continuation as a private company.

We applied a percentage probability weighting to each of the above scenarios based on our expectations of the likelihood of each event. We then applied the PWERM in order to allocate the derived aggregate enterprise value to our common equity. The PWERM involves analyzing the probability weighted present value of expected future values considering the liquidity scenarios discussed above, as well as the respective rights of holders of our common stock and convertible preferred stock.

### Stock Option Grants

The following table presents stock options granted between January 1, 2013 and May 28, 2014:

<u>Date of Grant</u>	<u>Number of Shares Underlying Stock Options Granted</u>	<u>Exercise Price Per Common Share</u>	<u>Common Stock Fair Value Per Share on Grant Date</u>
January 23, 2013	50,000	\$ 1.32	\$ 1.32
June 25, 2013	477,750	1.89	1.89
September 25, 2013	824,974	1.89	1.89
October 24, 2013	282,250	1.89	1.89
November 20, 2013	186,125	1.89	1.89
January 24, 2014	128,255	1.89	4.48
April 9, 2014	146,500	6.29	6.29

We completed contemporaneous valuations of our common stock on August 31, 2012, March 31, 2013, December 31, 2013 and March 31, 2014, when the board of directors determined business events or transactions may have resulted in a change in the fair value of our common stock. The dates of our contemporaneous valuations have not always coincided with the dates of our stock-based compensation grants. In determining the exercise price of the options set forth in the table above, our board of directors considered, among other things, the most recent contemporaneous valuations of our common stock and our assessment of additional objective and subjective factors it believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the recent contemporaneous valuations and the grant dates included, when available, the prices paid in recent transactions involving our equity securities, our operating and financial performance and current business conditions.

#### **Warrants to purchase redeemable securities**

In September 2008, we issued warrants to In-Q-Tel, Inc. that were immediately exercisable for 174,530 and 3,612 shares of our series B preferred stock, at an exercise price per share of \$3.3232 and \$4.65, respectively. In addition, in connection with the loan and security agreement with Silicon Valley Bank, as amended, we issued Silicon Valley Bank warrants that are exercisable for 13,769 shares of series A-2 preferred stock, 9,036 shares of our series B preferred stock and 19,780 shares of series D preferred stock at an exercise price per share of \$2.9050, \$3.3232 and \$4.55, respectively. In May 2011, in connection with a security agreement dated May 9, 2011 with Massachusetts Development Finance Agency, we issued a warrant to Massachusetts Development Finance Agency that is exercisable for 30,000 shares of our series C preferred stock, at an exercise price per share of \$3.6608.

These warrants are exercisable into securities that are subject to redemption provisions that are outside of our control. Therefore, the warrants are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense), net. We measure the fair value of our warrant liability based on input from management and the board of directors, which utilized an independent valuation of enterprise value utilizing an analytical valuation model. The valuations we obtained were prepared in accordance with the guidelines in the Practice Aid. We generally use an income approach to determine the enterprise value. We considered the various methods for allocating the enterprise value across our classes and series of capital stock to determine the fair value of our common stock at each valuation date. We used an OPM to determine the fair value of the warrant liability at December 31, 2012. We used a hybrid of an OPM and a PWERM to determine the fair value of the warrant liability at December 31, 2013 and March 31, 2014. Each valuation methodology includes estimates and assumptions that require our judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the *in vitro* diagnostics industry sector, the prices at which we sold shares of preferred stock, the superior rights and preferences of securities at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company.

Pursuant to the terms of these warrants, in connection with the closing of this offering, the warrants will be automatically exercisable on a cashless "net exercise" basis, where the holder receives the net value of the warrant in shares of common stock based on a formula using the initial public offering price. The warrants otherwise terminate upon the closing of this offering.

#### **Emerging Growth Company Status**

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards

would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission, or SEC, rules.

#### **Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risk related to changes in interest rates. As of March 31, 2014, we had cash and cash equivalents of \$23.7 million held primarily in money market funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. We are also subject to interest rate risk from the loans under our credit facility with Silicon Valley Bank that bear interest at an annual rate equal to the greater of (a) the prime rate (as reported in the Wall Street Journal at the time of funding) plus 3.0% and (b) 6.25%.

## BUSINESS

### Overview

We are an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. We are using our T2 Magnetic Resonance platform, or T2MR, to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter, or CFU/mL. Our initial development efforts utilizing T2MR target sepsis and hemostasis, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. We have completed a pivotal clinical trial for our T2Dx diagnostic instrument and our T2Candida panel, which have the ability to rapidly identify the five clinically relevant species of *Candida*, a fungal pathogen known to cause sepsis. On May 27, 2014, we submitted a *de novo* petition to the U.S. Food and Drug Administration, or the FDA, requesting an order authorizing us to market T2Dx and T2Candida in the United States. Upon receipt of marketing authorization from the FDA, we intend to commercialize T2Dx and T2Candida and our goal is to launch these product candidates commercially in the United States in the first half of 2015. Our next two diagnostic applications are called T2Bacteria and T2HemoStat, which are focused on bacterial sepsis infections and hemostasis, respectively. We plan to initiate clinical trials in the second half of 2015 for T2Bacteria and in the first half of 2016 for T2HemoStat. We expect that existing reimbursement codes will support our sepsis and hemostasis product candidates, that we will have no need to seek new reimbursement codes, and that the anticipated economic savings associated with our sepsis products will be realized directly by hospitals.

Sepsis is one of the leading causes of death in the United States and the most expensive hospital-treated condition. Most commonly afflicting immunocompromised, critical care and elderly patients, sepsis is a severe inflammatory response to a bacterial or fungal infection with a mortality rate of approximately 30%. According to data published by the U.S. Department of Health and Human Services for 2011, the cost of sepsis is over \$20 billion in the United States, or approximately 5% of the total aggregate costs associated with domestic hospital stays. Sepsis is typically caused by one or more of five *Candida* species or over 25 bacterial pathogens, and effective treatment requires the early detection and identification of these specific target pathogens in a patient's bloodstream. Today, sepsis is typically diagnosed through a series of blood cultures followed by post-blood culture species identification. This method has substantial diagnostic limitations that lead to a delay of up to several days in administration of targeted treatment and the incurrence of unnecessary hospital expense. Without the ability to rapidly identify pathogens, physicians typically start treatment of at-risk patients with broad-spectrum antibiotics, which can be ineffective and unnecessary and have contributed to the spread of antimicrobial resistance. According to a study published by *Critical Care Medicine* in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%.

We believe our sepsis product candidates will redefine the standard of care in sepsis management while lowering healthcare costs by improving both the precision and the speed of detection of sepsis-causing pathogens. According to a study published in the *Journal of Clinical Microbiology* in 2010, targeted therapy for patients with bloodstream infections can be delayed up to 72 hours due to the wait time for blood culture results, leading to the conclusion that more-rapid identification of the causative organism would be highly desirable to facilitate targeted treatment in

the critical phase of septic illness. In another study published in *Clinical Infectious Diseases* in 2012, the delayed administration of appropriate anti-fungal therapy was associated with higher mortality among patients with septic shock attributed to *Candida* infection and, on that basis, the study stated that more rapid and accurate diagnostic techniques appear to be needed. Our pivotal clinical trial demonstrated that T2Candida can deliver actionable results as fast as three hours, with an average time to result of 4.2 hours, rather than the two to five days typically required for blood-culture-based diagnostics, which we believe will enable physicians to make treatment decisions and administer targeted treatment to patients on an accelerated basis. We believe that T2Bacteria will also deliver actionable results within these timeframes because this diagnostic panel is designed to run on the same instrument as T2Candida.

*Candida* has an average mortality rate of approximately 40%. According to a study published in *Antimicrobial Agents and Chemotherapy* in 2010, this mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. In a study published in the *American Journal of Respiratory and Critical Care Medicine* in 2009, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the average cost of care by approximately \$30,000 per patient. We expect the anticipated economic savings associated with our sepsis product candidates will be realized directly by hospitals, as the diagnosis and treatment of sepsis patients in the United States in a hospital inpatient setting is currently reimbursed on an inpatient basis under existing diagnosis-related group, or DRG, codes. These codes provide hospitals with a fixed-sum reimbursement for all items and services provided to the patient during a single hospitalization. Therefore, we do not believe we will need to seek new reimbursement codes for our sepsis product candidates.

Another significant unmet clinical need that we believe can be addressed by T2MR is the timely diagnosis and management of impaired hemostasis, which is a potentially life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. For critical trauma patients with impaired hemostasis, diagnostic results are typically required in fewer than 30 minutes to aid clinicians in making the most effective treatment decisions. The need for rapid diagnosis is not met by current diagnostic methods, which typically involve multiple instruments and can take hours to process a patient specimen. As a result, physicians often make critical decisions for treatment of impaired hemostasis with limited or no diagnostic data.

We believe our combined initial addressable market opportunity for sepsis and hemostasis is over \$3 billion in the United States alone, when the market opportunity for T2Candida, T2Bacteria and our initial hemostasis diagnostic panel is combined. Within the sepsis market in the United States, we estimate that there are approximately 6.75 million critical care and immunocompromised patients who present with symptoms and are at high risk for a bloodstream infection who would be appropriate to be tested by our T2Candida panel. These patients, along with approximately two million additional patients who receive treatment in the emergency room setting, are also highly susceptible to bacterial infections, for a total of approximately 8.75 million patients who would be appropriate to be tested by our T2Bacteria panel. Within the hemostasis market, for trauma alone, there are over three million patients in the United States annually who present with symptoms of impaired hemostasis. These patients often require rapid and frequent hemostasis assessments to determine the presence and severity of abnormal coagulation, or blood clotting. As a result, the typical patient is tested at least three times during a hospital visit, which we estimate results in at least nine million diagnostic tests annually.

## **Our Strategy**

T2MR enables rapid and sensitive direct detection of a range of targets, and we believe it can be used in a variety of diagnostic applications that will improve patient outcomes and reduce



healthcare costs. Our objective is to establish T2MR as a standard of care for clinical diagnostics. To achieve this objective, our strategy is to:

- **Seek Marketing Authorization from the FDA for T2Dx and T2Candida.** We have completed a pivotal clinical trial for T2Dx and T2Candida and, on May 27, 2014, we submitted a *de novo* petition to the FDA for marketing authorization. We are targeting a commercial launch of both products in the first half of 2015. We also expect to seek regulatory clearance and approvals for these product candidates in European and other international markets beginning in the second half of 2014.
- **Drive Commercial Adoption of Our Sepsis Products by Demonstrating Their Value to Physicians, Laboratory Directors and Hospitals.** We expect our product candidates to meaningfully improve patient outcomes while reducing costs to hospitals. We intend to establish a targeted, direct sales force in the United States, which will initially focus on educating physicians and demonstrating our clinical and economic value proposition to hospitals that have the highest populations of at-risk critical care and immunocompromised patients. We believe a sustained focus on these hospitals will drive adoption of T2Dx, T2Candida and future T2MR-based diagnostics. As a part of this effort, we will continue to work with thought leaders, conduct clinical and health economic studies and seek publication and presentation of these studies.
- **Establish a Recurring, Consumables-Based Business Model.** We intend to pursue a consumables-based business model for our products by securing placements of our T2Dx instrument at hospitals and driving utilization of our diagnostic panels starting with T2Candida. We believe this strategy will foster a sustainable and predictable business model with recurring revenue streams.
- **Broaden Our Addressable Markets in Sepsis and Hemostasis.** Our product development pipeline includes additional instruments and diagnostic panels that provide near-term and complementary market expansion opportunities. Our next sepsis product candidate will focus on bacterial infections, will run on T2Dx and is expected to address the same high-risk patients as T2Candida, while also expanding our reach to a new patient population at increased risk for bacterial sepsis infections. We also are utilizing T2MR to address the challenges of providing rapid hemostasis monitoring. We expect to initiate pivotal clinical trials for our bacterial diagnostic panel, T2Bacteria, and our hemostasis instrument and diagnostic panel, T2Stat and T2HemoStat in the second half of 2015 and the first half of 2016, respectively. We are targeting to commercialize these product candidates in 2017 after obtaining marketing authorization or regulatory clearance.
- **Broaden Our Addressable Markets Beyond Sepsis and Hemostasis.** We intend to expand our product offerings by applying T2MR to new applications beyond sepsis and hemostasis. We plan to conduct internal development and to work with thought leaders, physicians, clinical researchers and business development partners to pursue new applications for T2MR. We believe the benefits of our proprietary technology, including the ability to rapidly and directly detect a broad range of targets, in a wide variety of sample types, will have potential applications within and outside of the *in vitro* diagnostics market, including environmental, food safety, industrial and veterinary applications.
- **Drive International Expansion.** If we receive marketing authorization from the FDA or other regulatory approvals, we plan to commercialize our product candidates in European and other international markets. We are in the process of developing distribution and commercialization strategies for these markets.

## Our Technology Platform

### **T2 Magnetic Resonance Platform Overview**

We have built an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. T2MR is a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. Our proprietary platform is capable of detecting a variety of targets, including:

- molecular targets, such as DNA;
- immunodiagnosics, such as proteins; and
- a broad range of hemostasis measurements.

For molecular and immunodiagnosics targets, T2MR utilizes advances in the field of nanotechnology by deploying particles with magnetic properties that enhance the magnetic resonance signals of specific targets. When particles coated with target-specific binding agents are added to a sample containing the target, the particles bind to and cluster around the target. This clustering changes the microscopic environment of water in that sample, which in turn alters the magnetic resonance signal, or the T2 relaxation signal that we measure, indicating the presence of the target.

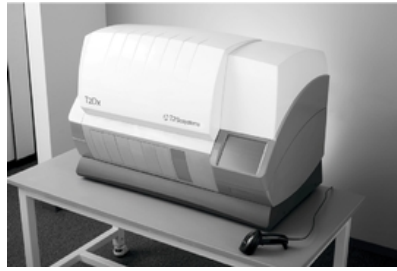
For hemostasis measurements, particles are not required because T2MR is highly sensitive to changes in viscosity in a blood sample, such as clot formation, stabilization or dissipation, which changes the T2 relaxation signal. This enables the rapid identification of clinically relevant hemostasis changes.

We also believe T2MR is the first technology that can rapidly and accurately detect the presence of molecular targets within samples without the need for time- and labor-intensive purification or extraction of target molecules from the sample, such as that required by traditional polymerase chain reaction, or PCR, where 90% or more of the target can be lost. We can eliminate these steps because the T2 relaxation signal is not compromised or disrupted by the sample background, even the highly complex sample background that is present after a target amplification process, such as thermocycling. This enables T2MR's low limit of detection, such as 1 CFU/mL, compared to the 100 to 1,000 CFU/mL typically required for PCR-based methods. Over 100 studies published in peer-reviewed journals have featured T2MR in a breadth of applications, including the direct detection and measurement of targets in various sample types, such as whole blood, plasma, serum, saliva, sputum and urine. We believe the potential applications for T2MR extend within and outside of the *in vitro* diagnostics market, including environmental, food safety, industrial and veterinary applications.

### **Our Instruments**

Utilizing T2MR, we have developed T2Dx, a bench-top instrument for sepsis and other applications, and we are developing T2Stat, a compact, fully integrated instrument for hemostasis applications.

T2Dx



T2Dx is an easy-to-use, bench-top instrument that is capable of running a broad range of diagnostic tests and is fully automated from patient sample input to result, eliminating the need for manual work flow steps such as pipetting that can introduce risks of cross-contamination. To perform a diagnostic test, the patient sample tube is snapped onto our disposable test cartridge, which is pre-loaded with all necessary reagents. The cartridge is then inserted into T2Dx, which automatically processes the sample and then delivers a diagnostic test result.

The initial panels designed to run on T2Dx are T2Candida and T2Bacteria, which are focused on identifying life-threatening pathogens associated with sepsis. We recently completed our pivotal clinical trial for T2Dx and T2Candida, and expect to initiate pivotal clinical trials for T2Bacteria in the second half of 2015.

T2Stat

We are also applying T2MR to develop T2Stat, which we believe will be the first compact, fully integrated instrument capable of rapidly providing comprehensive hemostasis measurements. T2Stat will run our T2HemoStat panel, which includes a broad set of hemostasis measurements, including platelet function and clotting time. We expect to initiate a pivotal clinical trial for T2Stat and T2HemoStat in the first half of 2016.

The following table reflects our product candidate pipeline currently in development:

Development	Validation	Pivotal Trial	Expected FDA Filing
<b>Instruments</b>			
T2Dx (infectious disease)			Submitted on May 27, 2014
T2Stat (hemostasis)		1H 2016	2017
<b>Diagnostics</b>			
T2Candida (sepsis)			Submitted on May 27, 2014
T2Bacteria (sepsis)		2H 2015	2016
T2HemoStat (hemostasis)		1H 2016	2017

## Sepsis

### Overview

Sepsis is an illness in which the body has a severe, inflammatory response to a bacterial or fungal infection. It is a life-threatening condition to which individuals with weakened immune systems or chronic illnesses are highly susceptible. Sepsis can lead to shock and organ failure, and is a leading cause of death in the United States with a mortality rate of approximately 30%, almost double the mortality rate of acute myocardial infarction, or heart attack.

In 2013, the U.S. Department of Health and Human Services reported that sepsis is the most expensive hospital-treated condition in the United States, with an economic burden to hospitals exceeding \$20 billion annually, almost double that of acute myocardial infarction. The high cost of treating sepsis is primarily driven by the extended hospitalization of patients. We believe there are many effective, targeted therapeutic choices that could reduce overall hospitalization costs if applied earlier, but clinicians need to more rapidly identify the specific sepsis-causing pathogens in order to make more informed, targeted treatment decisions. Today, the diagnostic standard to identify these pathogens is blood culture-based, despite typically requiring two to five days to generate results.

The following table reflects key statistics from the 2013 U.S. Department of Health and Human Services study regarding the five most expensive hospital-treated conditions:

Rank	Condition	U.S. hospital costs (in billions)	Percentage of total inpatient costs
1	Sepsis	\$ 20.3	5.2%
2	Osteoarthritis	14.8	3.8
3	Complication of device, implant or graft	12.9	3.3
4	Liveborn	12.4	3.2
5	Acute myocardial infarction (heart attack)	11.5	3.0

Over 1.6 million individuals are diagnosed with sepsis each year, 1.35 million of whom are at high risk for infection due to their suppressed immune system or their presence in critical care units. Virtually all of these patients are rapidly treated with broad-spectrum antibiotic drugs because there is no diagnostic manner for determining the type of infection. Of these 1.35 million patients with sepsis and at high risk for infection, approximately 40% do not respond to broad-spectrum antibiotic treatment. Of these patients that are non-responsive, approximately 25% of them have a *Candida* infection, with the remaining patients having a bacterial infection. Broad-spectrum antibiotics do not treat these *Candida* and bacterial infections as more targeted drugs are required.

We estimate that approximately 15 million patients are tested for blood stream infections in the United States annually. Of these, approximately 6.75 million are at high risk for a *Candida* infection and an additional two million, or approximately 8.75 million, in total are at high risk for a bacterial infection. We believe that our sepsis product candidates have the potential to enable clinicians to make earlier therapeutic decisions that can reduce the mortality rate for sepsis by over 50% and save the hospitals an estimated \$12 billion annually by testing all high risk patients with T2Candida and T2Bacteria.

There is also a significant market opportunity outside the United States for improved sepsis diagnosis, as this disease burdens other countries with similarly high mortality rates and high costs. Each year, over 18 million cases of sepsis are diagnosed worldwide, with estimated mortalities exceeding five million patients, making it a leading cause of death worldwide.

### Limitations of Traditional In Vitro Diagnostics for Sepsis

The current standard for identifying bloodstream infections that cause sepsis requires a series of lengthy and labor-intensive analyses that begin with blood culture. Completing a blood culture requires a large volume of a patient's blood, typically 20 mLs or more, which is obtained in two 10 mL draws and placed into two blood culture bottles containing nutrients formulated to grow fungi and bacteria. Before blood culture indicates if a patient is infected, pathogens typically must reach a concentration of 1,000,000 to 100,000,000 CFU/mL. This growth process typically takes two to five days because the pathogen's initial concentration in the blood specimen is often less than 10 CFU/mL. A negative test result always requires a minimum of five days. A positive blood culture typically means that some pathogen is present, but additional steps must be performed to identify the specific pathogen in order to provide targeted therapy. These additional steps, which typically must be performed by a highly trained technician, may involve any of (i) a staining procedure for inspection on a microscope slide, (ii) PCR amplification and (iii) mass spectrometry. These steps require a preceding positive blood culture specimen because they need a high concentration of cells generated by the blood culture process for analysis.

For PCR-based diagnostics, there is a requirement for extraction of target cells from the sample into a clear solution, where 90% or more of the cells can be lost. Extraction into a clear solution is needed because existing diagnostic detection methods cannot detect the targeted pathogen due to the complex background of the sample itself. While PCR amplifies the target signal, this loss of target cells impairs the ability to detect, resulting in typical limits of detection of 100 to 1,000 CFU/mL, which is insufficient for species-specific sepsis diagnostics.

Blood culture-based diagnostics have substantial limitations, including:

- **Time to Result Delays Targeted Treatment.** Blood culture-based diagnostics typically require a minimum of two and as many as five or more days to identify a pathogen species, and blood culture always requires at least five days to generate a negative test result.
- **Antimicrobial Therapy Can Cause False Negative Results.** Antimicrobial therapies may be administered to a patient prior to taking a blood sample. As a result, the therapeutic agent is contained in the blood sample and its ability to stop or slow the growth of pathogens can delay or completely inhibit the growth of the pathogen during the blood culture process leading to time delays in detection or false negative results.
- **Slow-Growing Pathogens Can Cause False Negative Results.** Some sepsis pathogens grow slowly or not at all and can require up to five or more days to reach sufficient concentrations to be detected by blood culture-based diagnostics. Blood culture procedures are typically stopped after five days and declared negative. Often, pathogens that grow too slowly are not detected by blood culture during this time frame, leading to a false negative diagnosis. For example, *C. glabrata*, one of the most lethal species of *Candida* due to its growing resistance to antifungal therapy, often requires more than five days of growth to reach a detectable concentration, and therefore is frequently undetected by blood culture.
- **Labor-Intensive Workflow Increases Costs and May Delay Targeted Treatment.** Blood culture is only the first step in identifying a pathogen that causes sepsis. After a blood culture is determined to be positive, highly trained technicians are required to perform multiple post-culture procedures on the blood culture specimen to identify the specific pathogen. These additional procedures can be expensive and time-consuming and may delay targeted treatment.

Given the typical two- to five-day time to result for blood culture-based diagnostics, the first therapy for a patient at risk of sepsis is often broad-spectrum antibiotics, which treat some but not all bacteria types and do not address fungal infections. Some physicians may use first-line, antifungal therapy for patients at very high risk for fungal infection, or use antifungal therapy if the

patient is not responding to broad-spectrum antibiotics while they are still awaiting the blood culture-based result. This therapeutic approach may still not treat the growing number of patients infected with the antimicrobial-resistant species nor may it be the best choice, as the type of therapy is dependent on the specific pathogen causing the infection, which is unknown.

This inefficient therapeutic approach has resulted in unnecessary treatment of a significant number of high-risk patients with expensive and often toxic therapies that can worsen a patient's condition. Such treatments may extend for many days while clinicians await blood culture-based diagnostic results. The overuse of ineffective, or even unnecessary, antimicrobial therapy is also the driving force behind the spread of antimicrobial-resistant pathogens, which the U.S. Centers for Disease Control and Prevention, or the CDC, recently called "one of our most serious health threats." The CDC has specifically noted increasing incidence of *Candida* infections due to azole- and echinocandin-resistant strains and considers it a "serious" threat level. According to the CDC, at least two million people in the United States acquire serious infections each year that are resistant to one or more of the antimicrobial therapies used to treat these patients. At least 23,000 of these people are estimated to die as a direct result of the resistant infections and many more may die from other conditions that are complicated by a resistant infection. Further, antimicrobial-resistant infections add considerable and avoidable costs to the already overburdened U.S. healthcare system, with the total economic cost estimated to be as high as \$20 billion in excess of direct healthcare costs, with additional costs to society as high as \$35 billion, due to lost productivity.

### **Our Solution**

T2MR delivers what we believe no other technology can: a rapid, sensitive and simple diagnostic platform that enables sepsis applications, including T2Candida and T2Bacteria, that can identify specific sepsis pathogens directly from an unpurified blood sample in hours instead of days at a level of accuracy equal to or better than blood culture-based diagnostics. We believe T2MR sepsis applications provide a pathway for more rapid and targeted treatment of infections, potentially reducing the mortality rate by as much as 75% if a patient is treated within 12 hours of suspicion of infection and significantly reducing the cost burden of sepsis. Each year, approximately 500,000 patients in the United States die from sepsis. According to a study published by *Critical Care Medicine* in 2006, in sepsis patients with documented hypotension, administration of effective antimicrobial therapy within the first hour of detection was associated with a survival rate of 79.9% and, over the ensuing six hours, each hour of delay in initiation of treatment was associated with an average decrease in survival of 7.6%; the survival rate for septic patients who remained untreated for greater than 36 hours was approximately 5%.

We believe T2MR sepsis applications address a significant unmet need in *in vitro* diagnostics by providing:

- **Limits of Detection as Low as 1 CFU/mL.** T2MR is the only technology that can enable identification of sepsis pathogens directly from a patient's blood sample at limits of detection as low as 1 CFU/mL.
- **Rapid and Specific Results As Fast As Three Hours.** T2MR is the only technology that can enable species-specific results for pathogens associated with sepsis, directly from a patient's blood sample, without the need for blood culture, to deliver actionable results as fast as three hours.
- **Accurate Results Even in the Presence of Antimicrobial Therapy.** T2MR is the only technology that can reliably detect pathogens associated with sepsis, including slow-growing pathogens, such as *C. glabrata*, directly from a patient's blood sample, even in the presence of an antimicrobial therapy.
- **Easy-to-Use Platform.** T2MR eliminates the need for sample purification or extraction of target pathogens, enabling sample-to-result instruments that can be operated on-site by hospital staff, without the need for highly skilled technicians.

Our first product candidates, T2Dx and T2Candida, focus on the most lethal form of common blood stream infections that cause sepsis, *Candida*, which has an average mortality rate of approximately 40%. According to a 2005 report published in *Antimicrobial Agents and Chemotherapy*, this high mortality rate can be reduced to 11% with the initiation of targeted therapy within 12 hours of presentation of symptoms. Currently, a typical patient with a *Candida* infection averages 40 days in the hospital, including nine days in intensive care, resulting in an average cost per hospital stay of over \$130,000 per patient. In a study published in the *American Journal of Respiratory and Critical Care Medicine* in 2009, providing targeted antifungal therapy within 24 hours of the presentation of symptoms decreased the length of hospital stay by approximately ten days and decreased the average cost of care by approximately \$30,000 per patient. In addition, many hospitals initiate antifungal drugs, such as Caspofungin or Micafungin, while waiting for blood culture-based diagnostic results. We estimate this practice costs approximately \$500 per patient and is currently in use for over 40% of high-risk patients on average and for all high-risk patients in some hospitals. A negative result from T2Candida can provide timely data allowing physicians to avoid unnecessary antifungal treatment and potentially reduce the treatment cost further.

We believe that by identifying the specific species of *Candida*, physicians can administer the most effective therapy, which will significantly improve patient outcomes and reduce hospital costs. We further believe that the adoption of T2Dx and T2Candida can decrease both the high mortality rate and excessive costs of *Candida* infections because these products can enable clinicians to make earlier and more informed decisions by providing positive test results to direct therapy and negative test results to reduce the use of antifungal drugs.

We are also developing T2Bacteria, a multiplex diagnostic panel that detects the major bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics. T2Bacteria will also run on T2Dx, and is expected to address the same approximately 6.75 million symptomatic high-risk patients, as T2Candida while also expanding our reach to a new population of patients who are at increased risk for bacterial infections, including an additional two million people presenting with symptoms of infection in the emergency room setting. We expect that T2Bacteria will achieve similar performance capabilities and provide similar benefits as T2Candida.

## **Clinical Utility**

### *direcT2 Clinical Trial*

We recently completed a pivotal clinical trial for our T2Dx diagnostic instrument and our T2Candida panel, or the direcT2 trial, and have provided the results of that trial to the FDA in conjunction with our *de novo* petition requesting an order authorizing us to market T2Dx and T2Candida. Our direcT2 trial consisted of two patient arms. The first arm, known as the Prospective Arm, consisted of 1,501 samples from patients with a possible infection. The second arm, known as the Contrived Arm, consisted of 300 samples, of which 250 patient specimens were labeled contrived because each contained a known quantity of *Candida* CFUs that were manually added to each sample at clinically relevant concentrations, while the remaining 50 patient specimens were specifically known not to contain *Candida*. The direcT2 trial was designed to evaluate the sensitivity and specificity of T2Candida on the T2Dx instrument.

Sensitivity is the percent concordance, or the percentage of sample results that agree with a reference, or comparative, method for positive results. Specificity is the percent concordance to a reference method for negative results. If a sample does not agree with the result of a referenced method, it is considered discordant. In our clinical trial, the Prospective Arm was compared to blood culture and the Contrived Arm was compared to the known state, which means that it was in the known presence or absence of added *Candida* organisms.

The design of the direcT2 trial was reviewed by the FDA as part of pre-submission communications. The purpose of the direcT2 trial was to determine the clinical performance of T2Candida running on the T2Dx by identifying the following:

- clinical specificity of T2Candida results as compared to *Candida* negative blood culture results in specimens collected from patients in the Prospective Arm;
- clinical specificity of T2Candida results as compared to *Candida* negative samples collected from patients in the Contrived Arm;
- clinical sensitivity of T2Candida results as compared to the known *Candida*-positive specimens collected from patients in the Contrived Arm; and
- clinical sensitivity calculations of T2Candida results compared to the *Candida*-positive blood culture results in specimens collected from patients in the Prospective Arm.

Key findings from the direcT2 trial are:

- the overall sensitivity (Prospective and Contrived Arm combined) of T2Candida was 91.1%;
- the average specificity of the three test results for the Prospective and Contrived Arms combined was 99.4% (see Table A) with the specificity by test result ranging from 98.9% to 99.9% (see Table B);
- in the Contrived Arm of the study, the average specificity was 99.8%, with the specificity by test result ranging from 99.6% to 100% (see Table C);
- in the Prospective Arm of the study, the average specificity was 99.3%, with the specificity by test result ranging from 98.8% to 99.9% (see Table C);
- in the Contrived Arm of the study, the average sensitivity was 91.6%, with the sensitivity by test result ranging from 88.0% to 94.0% (see Table C); and
- in the Prospective Arm of the study, the average sensitivity was 71.4% (see Table C).

In this study, we also observed the following:

- within the Prospective Arm, T2Candida accurately detected a rare co-infection in one study patient with *C. albicans* and *C. parapsilosis* in their bloodstream;
- T2Candida detected at least one infection that was not identified by blood culture, which was determined to be a *Candida* infection seven days after the T2Candida result was obtained. This case is considered a discordant result for the purposes of the FDA filing because of the disagreement between T2Candida and the blood culture-based results, despite the accurate identification by T2Candida, and it indicates that the true sensitivity and specificity of T2Candida may be higher than the reported values;
- the limit of detection, or LoD, of T2Candida was demonstrated to be 1 to 3 CFU/mL depending upon the species of *Candida* (see Table D). In the Contrived Arm of the study, T2Candida positively detected 97.9% of the samples spiked at and above the LoD while also detecting 72.6% of all samples spiked at concentration levels below the LoD (see Table E);
- in the Contrived Arm of the study, T2Candida detected 97% of cases at or above 1 CFU/mL and 70% of cases below 1 CFU/mL (see Table F);



- in the Contrived Arm of the study, T2Candida detected 98% of cases at or above clinically relevant concentrations of *Candida*, ranging from 95% to 100% detection depending on the *Candida* species (see Table G); and
- T2Candida demonstrated an average time to result of 4.2 hours.

50 known negative samples and 250 contrived samples (50 samples for each of the five *Candida* species included in the T2Candida panel) were prepared and run in a blinded manner at the same clinical sites used for processing the prospective samples. The positive contrived samples were prepared by spiking clinical isolates into individual patient specimens at concentrations determined through publications and discussions with the FDA to be equivalent to the clinical state of patients who presented with signs and symptoms of a *Candida* infection. 20% of the positive contrived samples were spiked at concentrations levels of less than 1 CFU/mL. The contrived samples were collected from patients referred for a diagnostic blood culture per routine standard of care — the same population of patients from whom prospective samples were collected. Unique isolates of the species were used for each patient sample, which means a total of 50 unique isolates were tested for each of the five species of *Candida* for a total of 250 unique isolates.

In addition to the pivotal clinical trial data that we have submitted to the FDA, we provided data from an analytical verification study to determine the LoD for each species identified by our T2Candida panel. The LoD was defined as the lowest concentration of *Candida* that can be detected in 95% of at least 20 samples tested at a single concentration.

The T2Candida panel reports three results, where species are grouped together according to their responsiveness to therapy. *Candida albicans* and/or *Candida tropicalis* are reported as a single result, *Candida parapsilosis* is a single result, and *Candida krusei* and/or *Candida glabrata* are reported as a single result. Specificity and sensitivity are calculated for each reported result.

There are five relevant species of *Candida*, each of which were analyzed in the direct2 trial. Each are listed in abbreviated form in the tables below. These species are *Candida albicans*, *Candida tropicalis*, *Candida parapsilosis*, *Candida krusei*, and *Candida glabrata*. The typical naming convention for a species is to abbreviate by using the first letter of the first word and the full second word, for example, *Candida krusei* is abbreviated as *C. krusei*. In the tables below, we also abbreviate each species name by the first letter of the second word, for example, *Candida albicans* and *Candida tropicalis* is *AT*.

The following tables illustrate the results of the direct2 trial. The primary sensitivity and specificity analysis is presented in Table A, followed by sub-analyses in Tables B and C. Additional data on the LoD and the time to results of T2Candida and T2Dx are included in the remaining tables.

**Table A**  
**T2Candida Performance Characteristics**

	<u>Overall Sensitivity</u>	<u>Overall Specificity</u>
Number of Tests (%)	234/257 (91.1%)	5114/5146 (99.4%)

**Table B**  
Overall Sensitivity and Specificity by Test

		95% Confidence Interval
<b>Specificity:</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	1679/1697 (98.9%)	98.3-99.4%
P ( <i>C. parapsilosis</i> )	1736/1749 (99.3%)	98.7-99.6%
K/G ( <i>C. krusei/C. glabrata</i> )	1699/1700 (99.9%)	99.7-100.0%
Total:	5114/5146 (99.4%)	99.1-99.6%
<b>Sensitivity:</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	96/104 (92.3%)	85.4-96.6%
P ( <i>C. parapsilosis</i> )	49/52 (94.2%)	84.1-98.8%
K/G ( <i>C. krusei/C. glabrata</i> )	89/101 (88.1%)	80.2-93.7%
Total:	234/257 (91.1%)	86.9-94.2%

**Table C**  
Study Arm Sensitivity and Specificity by Test

		95% Confidence Interval
<b>Specificity (Prospective tests):</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	1479/1497 (98.8%)	98.1-99.3%
P ( <i>C. parapsilosis</i> )	1487/1499 (99.2%)	98.6-99.6%
K/G ( <i>C. krusei/C. glabrata</i> )	1499/1500 (99.9%)	99.6-100.0%
Total:	4465/4496 (99.3%)	99.0-99.5%
<b>Sensitivity (Prospective tests):</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	2/4 (50.0%)	6.8-93.2%
P ( <i>C. parapsilosis</i> )	2/2 (100.0%)	15.8-100.0%
K/G ( <i>C. krusei/C. glabrata</i> )	1/1 (100.0%)	2.5-100.0%
Total:	5/7 (71.4%)	29.0-96.3%
<b>Specificity (Contrived tests):</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	200/200 (100.0%)	98.2-100.0%
P ( <i>C. parapsilosis</i> )	249/250 (99.6%)	97.8-100.0%
K/G ( <i>C. krusei/C. glabrata</i> )	200/200 (100.0%)	98.2-100.0%
Total:	649/650 (99.8%)	99.1-100.0%
<b>Sensitivity (Contrived tests):</b>		
A/T ( <i>C. albicans/C. tropicalis</i> )	94/100 (94.0%)	87.4-97.8%
P ( <i>C. parapsilosis</i> )	47/50 (94.0%)	83.5-98.7%
K/G ( <i>C. krusei/C. glabrata</i> )	88/100 (88.0%)	80.0-93.6%
Total:	229/250 (91.6%)	87.4-94.7%

**Table D**  
**T2Candida Limit of Detection**

Species	Final LoD CFU/mL
<i>C. albicans</i>	2
<i>C. tropicalis</i>	1
<i>C. parapsilosis</i>	3
<i>C. glabrata</i>	2
<i>C. krusei</i>	1

**Table E**  
**Sensitivity Sub-Analysis: Sensitivity by Species Relative to LoD**

Species	LoD (CFU/ml)	<sup>3</sup> LoD		< LoD	
		Sensitivity	95% Confidence Interval	Sensitivity	95% Confidence Interval
<i>C. albicans</i>	2	39/39 (100.0%)	91.0-100.0%	9/11 (81.8%)	48.2-97.7%
<i>C. glabrata</i>	2	35/37 (94.6%)	81.8-99.3%	7/13 (53.8%)	25.1-80.8%
<i>C. krusei</i>	1	40/40 (100.0%)	91.2-100.0%	6/10 (60.0%)	26.2-87.8%
<i>C. parapsilosis</i>	3	32/32 (100.0%)	89.1-100.0%	15/18 (83.3%)	58.6-96.4%
<i>C. tropicalis</i>	1	38/40 (95.0%)	83.1-99.4%	8/10 (80.0%)	44.4-97.5%
Total:		184/188 (97.9%)	94.6-99.4%	45/62 (72.6%)	59.8-83.1%

**Table F**  
**Sensitivity Sub-Analysis: Sensitivity by Titer Level**

Species	<1 CFU/ml Sensitivity	1 - 10 CFU/ml Sensitivity	11 - 30 CFU/ml Sensitivity	31 - 100 CFU/ml Sensitivity
<i>C. albicans</i>	8/10 (80.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
<i>C. glabrata</i>	5/10 (50.0%)	16/18 (88.9%)	16/17 (94.1%)	5/5 (100.0%)
<i>C. krusei</i>	6/10 (60.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
<i>C. parapsilosis</i>	8/10 (80.0%)	17/18 (94.4%)	17/17 (100.0%)	5/5 (100.0%)
<i>C. tropicalis</i>	8/10 (80.0%)	16/18 (88.9%)	17/17 (100.0%)	5/5 (100.0%)
Total:	35/50 (70.0%)	85/90 (94.4%)	84/85 (98.8%)	25/25 (100.0%)

**Table G**  
**Sensitivity Sub-Analysis: Sensitivity by Species Relative to Clinically Relevant Concentrations**

Species	Clinically Relevant Concentration	Sensitivity † Relevant CFU	Sensitivity ‡ Relevant CFU
<i>C. tropicalis</i>	1-10 CFU/mL	80%	95%
<i>C. krusei</i>	11-30 CFU/mL	85.7%	100%
<i>C. glabrata</i>	11-30 CFU/mL	75%	96%
<i>C. albicans</i>	1-10 CFU/mL	80%	100%
<i>C. parapsilosis</i>	11-30 CFU/mL	89.3%	100%
Total		82.7%	98%

**Table H**  
**Time to species identification or negative result for T2MR and Blood Culture**

	Blood Culture	T2Dx
<b>Time to Results (hours)</b>		
Mean ± SD (N)	126.5 ± 27.3 (1470)	4.2 ± 0.9 (1470)
Median	121.0	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)
<b>Time to Positive Results<sup>(1,2)</sup> (hours)</b>		
Mean ± SD (N)	43.6 ± 11.1 (4)	4.4 ± 1.0 (4)
Median	46.1	4.6
(Min, Max)	(28.1, 54.1)	(3.2, 5.4)
<b>Time to Negative Results<sup>(1,2)</sup> (hours)</b>		
Mean ± SD (N)	126.7 ± 27.0 (1466)	4.2 ± 0.9 (1466)
Median	121.1	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)

(1) Includes samples that are 100% concordant for both methods (i.e. does not include discordant results).

(2) Refers to time to species identification or final negative result.

*Massachusetts General Hospital Study — Science Translational Medicine*

We co-authored a study with investigators from Massachusetts General Hospital, or MGH, to evaluate the sensitivity and specificity of T2MR to detect *Candida* compared to blood culture-based diagnostics. Results from the study were published in an article entitled "T2 Magnetic Resonance Enables Nanoparticle-Mediated Rapid Detection of Candidemia in Whole Blood" in *Science Translational Medicine* in 2013. In this study:

- T2MR was tested across 320 contrived whole blood samples, each containing one of the five clinically relevant species of *Candida*, and was able to detect each of the species at an LoD ranging from 1 to 3 CFU/mL.
- T2MR was tested across 24 whole blood specimens from patients exhibiting symptoms of sepsis, with eight *Candida* positive, eight bacteria positive and eight negative samples. Results showed 100% sensitivity and 100% specificity of T2MR when compared with blood culture results for identification of *Candida*.
- In patients with *Candida* treated with antifungal therapy, T2MR detected the presence of *Candida* in patient samples drawn up to four days after antifungal administration, while blood culture failed to identify the infection upon administration of antifungal therapy.

*University of Houston Study — Diagnostic Microbiology and Infectious Disease*

We sponsored an independent study at the University of Houston to directly compare the sensitivity and time to result of T2Candida running on T2Dx and blood culture-based diagnostics. In this study, contrived blood samples were split between T2Candida using T2Dx and standard blood culture. The study showed improved performance of T2Candida over blood culture in terms of speed and sensitivity. The following findings were published in an article entitled "Comparison of the T2Dx instrument with T2Candida Diagnostic Panel and Automated Blood Culture in the

Detection of *Candida* Species Using Seeded Blood Samples" in *Diagnostic Microbiology and Infectious Disease* in 2013:

- T2Candida detected all of the samples of *C. glabrata* at concentrations of 2.8 CFU/mL, while blood culture was not able to detect *C. glabrata* in any of the samples, even at a higher concentration of 11 CFU/mL and with the standard five-day run time.
- T2Candida detected all of the samples for all of the species of *Candida* at concentration levels of 3.1 to 11 CFU/mL.
- The average time to species identification was approximately three hours for T2Candida, as opposed to over 60 hours for blood culture.

The following table summarizes the results of our University of Houston study. The five relevant species of *Candida* were analyzed in the University of Houston study.

**Contrived blood samples at concentrations between 3.1 - 11 CFU/mL**

	Blood Culture (n=20 per species)	T2Candida (n=13-20 per species)
Average time to positive result	63.23 ± 30.27 hours	3 hours
	<i>C. albicans</i> = 100%	<i>C. albicans</i> = 100%
	<i>C. tropicalis</i> = 100%	<i>C. tropicalis</i> = 100%
Detection rate	<i>C. parapsilosis</i> = 100%	<i>C. parapsilosis</i> = 100%
	<i>C. glabrata</i> = 0%	<i>C. glabrata</i> = 100%
	<i>C. krusei</i> = 100%	<i>C. krusei</i> = 100%
Sensitivity		100%
Specificity		98%

**Hemostasis**

Another significant unmet clinical need is the diagnosis and management of impaired hemostasis, which is a life-threatening condition in which a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. Within the broader population of patients with symptoms of impaired hemostasis, there are over three million trauma patients in the United States annually. These trauma patients typically face life-threatening injuries or invasive surgical procedures. Approximately 25% of trauma patients have impaired hemostasis, which frequently goes undetected during the initial hospitalization. According to a study in the *Journal of the American College of Surgeons*, for trauma patients with symptoms of impaired hemostasis, mortality was reduced from 45% to 19% with more rapid delivery of therapy. Today, there is no hemostasis diagnostic method that can rapidly provide comprehensive results. We estimate that rapid, targeted treatment for trauma patients with impaired hemostasis can reduce healthcare costs in the United States by nearly \$2 billion each year due to more efficient utilization of scarce and expensive blood products and more rapid patient stabilization, reducing length of hospital stays by approximately 20%.

Because the hemostasis status of trauma patients changes frequently, patients are on average tested three times per trauma episode, which we estimate results in approximately nine million hemostasis tests performed annually on trauma patients in the United States alone. This unmet need represents an approximately \$500 million market opportunity, which will be the initial focus for T2Stat and T2HemoStat.

Existing hemostasis screening methods have a range of limitations. Such screening can require:

- up to 24 hours to provide a diagnosis;
- large volumes of blood from patients;
- as many as five separate instruments to provide comprehensive results;
- highly skilled technicians; and
- specialty laboratories.

T2Stat and T2HemoStat utilize T2MR and are designed to provide hemostasis measurements in less than 20 minutes. T2HemoStat is a comprehensive panel of diagnostic tests that can provide data across the hemostasis spectrum, including measurements of clotting time, platelet activity, clot contraction and clot lysis. We believe that T2HemoStat will be the first panel capable of rapidly identifying key coagulation, platelet and other hematologic factors directly from whole blood on a single, easy to operate, compact instrument that will provide all of the following benefits:

- comprehensive results in 20 minutes or less;
- results from clinical samples as small as a finger stick of blood;
- replacement of up to five instruments with one compact instrument;
- easy-to-use system, not requiring highly skilled technicians to operate; and
- small, tabletop instrument that can be used at the point of care.

We expect that existing DRG and Current Procedural Terminology, or CPT codes, will be used to facilitate reimbursement of our hemostasis diagnostic products.

While the panel of HemoStat diagnostic tests currently in development is focused on addressing the unmet need for trauma patients, T2HemoStat can be expanded to add diagnostic tests that can address the needs of the broader population of patients with impaired hemostasis.

We also believe T2MR will be able to identify novel biomarkers with important clinical utility. For example, in a 2014 peer-reviewed article featured on the cover of the journal, *Blood*, T2MR was used to identify a new clot structure that has potential as a novel biomarker which could provide additional actionable information to manage patients with impaired hemostasis after trauma.

### **Sales, Marketing and Distribution**

We intend to drive awareness and adoption of our T2MR technology and related products, if they achieve marketing authorization from the FDA or regulatory clearance, by building a direct sales force in the United States, initially targeting high-volume hospitals, and continuing to educate physicians, key decision makers and thought leaders through publishing scientific data in peer-reviewed journals, presenting at major industry conferences and conducting and supporting clinical studies.

The foundation of our commercialization strategy is to build an experienced, direct sales force consisting of approximately 15 commissioned representatives in the first year of launch. Our sales representatives, employing a clinical data-driven sales approach, will focus on the clinical performance of our products, if approved, the improved outcomes for patients and the economic value for hospitals, including customizable budgetary impact analysis. They will demonstrate the ease-of-use of our products and the advantages of our products over blood culture-based diagnostics. We will continue to invest in our direct sales force as we expand both the array of diagnostic panels and our customer reach.

Our sales force will sell T2Dx and T2Candida, if they are cleared by the FDA, directly to hospitals in the United States, initially targeting the 450 hospitals treating the largest number of high-risk patients. We estimate that these 450 centers annually treat an average of over 5,000 symptomatic patients at high risk for a *Candida* infection, representing over one-third of the expected market for T2Candida. If these leading institutions adopt our technology, we expect a positive network effect in the hospital community, accelerating adoption of T2Candida. We believe key aspects of Healthcare Reform, including the focus on cost containment, risk-sharing, and outcomes-based treatment and reimbursement, align with the value proposition of our sepsis products, contributing positively to their adoption. We believe the key decision-makers at hospitals will be infectious disease physicians, laboratory directors, the hospital pharmacy and hospital administrators. In response to the severity and complexity of managing bloodstream infections, a growing number of hospitals have instituted antimicrobial stewardship committees to control hospital practices related to infections, including the use of antibiotic and antifungal therapy. These committees typically include the key decision-makers, and we believe they will provide a central forum to present the benefits of our products. In addition, we plan to continue to publish scientific data in peer-reviewed journals, present at major industry conferences and conduct and support clinical trials to provide additional data relative to the performance of T2Candida to these decision-makers.

Outside of the United States, we expect to seek regulatory approvals in European and other international markets and to launch our platform through distributor partners who will deploy a similar model to our sales approach in the United States.

## **Manufacturing**

We manufacture our proprietary T2Dx instrument and our T2Candida reagent trays at our approximately 6,500 square foot manufacturing facility in Wilmington, Massachusetts. We perform all instrument and tray manufacturing and packaging of final components in accordance with applicable guidelines for medical device manufacturing. We outsource manufacturing of our T2Candida consumable cartridge to a contract manufacturing organization. Our particles are supplied by a sole source supplier, GE Healthcare. We believe we can secure arrangements with other suppliers on commercially reasonable terms for the products and parts we outsource.

We have implemented a quality management system designed to comply with FDA regulations and International Standards Organization, or ISO, standards governing medical device products. These regulations govern the design, manufacture, testing and release of diagnostic products as well as raw material receipt and control. Our key outsourcing partners are ISO-certified.

We plan to continue to manufacture components that we determine are proprietary or require special processes to produce, while outsourcing the manufacture of more commodity-like components. We expect to establish additional outsourcing partnerships as we manufacture more products. We believe our facility in Wilmington, Massachusetts is adequate to meet our current manufacturing needs and that additional manufacturing space is readily available for future expansion.

## **Intellectual Property**

We strive to protect and enhance the proprietary technologies that we believe are important to our business, and seek to obtain and maintain patents for any patentable aspects of our product candidates, including their methods of use and any other inventions that are important to the development of our business. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important proprietary technology, inventions and know-how related to our business, including our methods, processes and product candidate designs, and our ability to defend and enforce our patents, maintain our licenses to use

intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on trademarks, copyrights, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our product candidates. Protecting these rights is a primary focus in our relationships with other parties, and we seek to protect such rights, in part, by entering into confidentiality and non-disclosure agreements with such third parties and including protections for such proprietary information and intellectual property rights in our other contracts with such third parties, including material transfer agreements, licenses and research agreements.

We are the owner or licensee of an extensive portfolio of patents and patent applications and possess substantial know-how and trade secrets which protect various aspects of our business and product candidates. The patent families comprising our patent portfolio are primarily focused on protection of a range of general and specific attributes of our proprietary assay architecture and assay instrumentation for our T2Candida and T2Bacteria products, as well as protection of certain aspects of the conduct of the assays and detection of analytes. We also own several patent families covering various aspects of our T2HemoStat assay, including the assay architecture and conduct of the analysis. The issued patents in our patent families that cover T2Candida and T2Bacteria are expected to expire between 2023 and 2031, while additional pending applications in these families would be expected to expire, if issued, between 2023 and 2033. Our patent families covering T2HemoStat, if issued, will be expected to expire, between 2026 and 2033. In all cases, the expiration dates are subject to any extension that may be available under applicable law.

## **Patents**

We own 22 patent families, including 16 issued United States patents, 15 issued patents outside of the U.S., 27 pending U.S. patent applications, five pending Patent Cooperation Treaty, or PCT applications, and 33 pending patent applications outside of the U.S. We also hold an exclusive license to three patent families from MGH, including three issued U.S. patents, five issued patents outside of the U.S., three pending U.S. patent applications, and one pending application outside the U.S., which cover various aspects of our T2MR, T2Candida and T2Bacteria products.

### *T2Candida and T2Bacteria*

We are the owner or exclusive licensee of 11 issued U.S. patents and 11 pending U.S. patent applications, as well as 13 issued patents, two pending PCT applications and 11 pending patent applications in jurisdictions outside of the U.S., covering various aspects of T2Candida or T2Bacteria. In particular, U.S. Patent 8,569,078 (the '078 Patent), which is included within the patent rights covered by our exclusive license from MGH, covers our assay method architecture for our T2Candida and T2Bacteria product candidates. We are also the sole owner of issued U.S. patents and pending applications, including foreign counterparts in Australia, Canada, Europe, and Japan that are directed to the device instrumentation and certain components that are specific to the assay itself, including reagents and methods of detection of analytes. Our issued U.S. patents that cover aspects of our T2Candida and/or T2Bacteria product candidates are expected to expire between 2023 and 2031, with the '078 Patent expiring in 2023. In addition to the utility patents included in our patent portfolio, we are also the sole owner of issued design patents and pending applications in the U.S. and foreign jurisdictions that cover certain aspects of the design of our device cartridge and assay tubes.

### *T2HemoStat*

We are the owner of three pending U.S. patent applications, two pending PCT applications and nine pending patent applications in foreign jurisdictions covering various aspects of



T2HemoStat, including the device and methods for determining coagulation times and evaluating coagulopathies using the assay. If these applications proceed to issue, the U.S. claims that cover our T2HemoStat product candidates are expected to expire between 2026 and 2033.

#### **Patent Term**

The term of individual patents and patent applications listed in previous sections will depend upon the legal term of the patents in the countries in which they are obtained. In most countries, the patent term is 20 years from the date of filing of the patent application (or parent application, if applicable). For example, if an international PCT application is filed, any patent issuing from the PCT application in a specific country generally expires 20 years from the filing date of the PCT application.

#### **Proprietary Rights and Processes**

We rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We require all full-time and temporary employees, scientific advisors, contractors and consultants working for us who have access to our confidential information to execute confidentiality agreements in order to safeguard our proprietary technologies, methods, processes, know-how, and trade secrets. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. All of our full-time and temporary employees and independent contractors and consultants are also bound by invention assignment obligations, pursuant to which rights to all inventions and other types of intellectual property conceived by them during the course of their employment are assigned to us.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, consultants, scientific advisors, contractors, or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to provide competitive advantages. For more information, please see "Risks Related to Intellectual Property."

#### **Trademarks**

We seek trademark and service mark protection in key markets to safeguard our brand and the brands of our product candidates. We intend to file trademark registration applications in the U.S. and foreign jurisdictions to continue to strengthen our brand.

#### **License Agreements**

##### *License Agreement with Massachusetts General Hospital*

In 2006, we entered into an exclusive license agreement with MGH, pursuant to which MGH granted to us an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. In 2008 and 2011, we amended our agreement with MGH to add patent rights and to modify, among other things, our diligence and payment obligations.

We are required to use reasonable commercial efforts to develop and make available to the public products and processes covered by the agreement, and to achieve specified organizational,

development and commercialization milestones by specified dates. To date, we have met all of our diligence obligations pursuant to this agreement.

We paid MGH an upfront fee and issued to MGH shares of our common stock equal to a low single-digit percentage of our then-outstanding common stock, subject to limited adjustments to prevent dilution in certain circumstances. In addition, we are responsible for reimbursing MGH's costs associated with prosecution and maintenance of the patent rights licensed to us under the agreement. We will also be required to make payments for achievement of specified regulatory milestones with respect to products and processes covered by the agreement. In addition, we are required to pay an annual license maintenance fee, which is creditable against any royalty payments we are obligated to make to MGH under the agreement.

We will be required to pay royalties to MGH on net sales of products and processes that are covered by patent rights licensed to us under the agreement at percentages in the low single digits, subject to reductions and offsets in specified circumstances. The products and processes covered by the agreement include T2Candida, T2Bacteria and other particle-based T2MR panels that we may develop in the future. Our royalty obligations, if any, and their duration, will depend on the specific patent rights covering the product or process being sold, and the particular category of product or process, as noted above. With respect to T2Candida and T2Bacteria and other potential particle-based T2MR panels we may develop in the future, our obligation to pay royalties to MGH will expire upon the later of ten years after the first commercial sale of the first product or process in the particular category and the expiration of the patent rights licensed to us under the agreement. We will also be required to pay to MGH a low double-digit percentage of specified gross revenue that we receive from our sublicensees. In addition, we will be required to pay royalties to MGH of less than one percent on net sales of specified products and processes that are not covered by the patent rights licensed to us under the agreement. Our obligation to pay royalties to MGH with respect to such products and processes will expire upon the earlier of 12 years after the first commercial sale of the first such product or process and the termination by MGH of all of the licenses granted to us under the agreement.

We have the right to terminate our agreement with MGH for any reason upon 90 days' written notice to MGH. MGH may terminate our agreement in its entirety if we fail to make a payment required under the agreement and do not cure such failure within a specified time period, if we fail to maintain adequate insurance coverage or if we become insolvent. MGH may also terminate our agreement, with respect to a given category of products or processes, on 60 days' notice for our uncured breach with respect to such category of products or processes. Absent earlier termination, our agreement with MGH will remain in force until the later of the expiration or abandonment of the licensed patents and patent applications, and the expiration of our obligations under the agreement.

#### *Sales Agreement with GE Healthcare*

We are currently party to a supply and license agreement with GE Healthcare for the manufacture and supply by GE Healthcare of its proprietary superparamagnetic particles to be used in connection with our product candidates. This agreement with GE Healthcare also grants to us a non-exclusive, worldwide, non-royalty bearing, sublicensable license to use the supplied products for the purposes of research, development, manufacture and sale of our product candidates for *in vitro* industrial diagnostics, human diagnostics and veterinary diagnostics purposes, but not for use in therapeutics. The agreement contains other terms and conditions generally consistent with an agreement for the manufacture and supply of materials or products for use in the development and commercialization of biotechnology products such as our product candidates, including with respect to ordering, supply of such product in accordance with specifications, and quality assurance and quality control activities. We are obligated to meet certain minimum purchase requirements in each contract year of the agreement during the five-year term.

Either party may terminate the agreement immediately upon the insolvency of the other party, or for uncured breach of the agreement where termination is effective on receipt by the breaching party of a termination notice not less than 30 days after receipt of written notice of a breach. Absent earlier termination, our agreement with GE Healthcare will remain in force until December 31, 2015.

## Competition

We believe we are currently the only diagnostic company developing products with the potential to identify pathogens associated with bloodstream infections in a variety of unpurified patient sample types at limits of detection as low as 1 CFU/mL. Our principal competition will be from a number of companies that offer platforms and applications in our target sepsis and hemostasis markets, most of which are more established commercial organizations with considerable name recognition and significant financial resources.

Companies that currently provide traditional blood culture-based diagnostics include Becton Dickinson & Co. and bioMerieux, Inc. In addition, companies offering post-culture species identification using both molecular and non-molecular methods include bioMerieux, Inc., Bruker Corporation, Cepheid and Siemens AG. These post-culture competitors rely on a positive result from blood culture in order to perform their tests, significantly prolonging their results when compared to T2MR. Some of the products offered by our competitors require hours of extensive hands-on labor by an operator, while some rely on high concentrations of pathogens present in a positive blood culture, which can require a final concentration of at least 1,000,000 CFU/mL. In addition, there may be a number of new market entrants in the process of developing competing technologies.

We believe that we have a number of competitive advantages, including:

- T2MR's ability to detect targets directly in complex and high volume samples, eliminating the need for sample extraction and purification;
- T2MR's ability to detect a broad range of targets, providing a wide variety of potential applications both within and outside of the *in vitro* diagnostics market;
- T2MR's ability to provide rapid and highly-sensitive diagnostic results, which can provide timely information to assist physicians and hospitals to make therapeutic decisions that can improve patient outcomes and reduce healthcare costs;
- our ability to develop easily operable products for end users;
- our initial applications in the field of sepsis that we believe will not require separate reimbursement codes due to the established payment and reimbursement structure in place; and
- our initial applications may provide substantial economic benefits to hospitals that can accrue the savings related to the rapid treatment of sepsis patients.

## Government Regulation

Our products under development and our operations are subject to significant government regulation. In the United States, our products are regulated as medical devices by the FDA and other federal, state, and local regulatory authorities.

## **FDA Regulation of Medical Devices**

The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

In the United States, numerous laws and regulations govern all the processes by which medical devices are brought to market and marketed. These include the Federal Food, Drug and Cosmetic Act, or FDCA, and the FDA's implementing regulations, among others.

### **FDA Pre-market Clearance and Approval Requirements**

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* down classification, or pre-market approval from the FDA, unless specifically exempted by the FDA. The FDA classifies all medical devices into one of three classes. Devices deemed to pose the lowest risk are categorized as either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) pre-market notification submission requesting clearance of the device for commercial distribution in the United States. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device are categorized as Class III. These devices require submission and approval of a premarket approval, or PMA, application.

#### **510(k) Clearance Process**

To obtain 510(k) clearance, we must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously-cleared 510(k) device, a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of pre-market approval applications, or is a device that has been reclassified from Class III to either Class II or I. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support

substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k)s and additional requirements that may significantly impact the process.

#### *Pre-market Approval Process*

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, clinical trials, manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR, which imposes elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

#### *De novo Classification Process*

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on

the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. We plan to utilize the *de novo* classification process to obtain marketing authorization for our T2Dx and T2Candida devices under development, which we believe will be placed within Class II.

#### *Clinical Trials*

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards, or IRBs, at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

#### *Pervasive and Continuing U.S. Food and Drug Administration Regulation*

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

- the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

- post-market surveillance including Medical Device Reporting, which requires manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements may result in enforcement action by the FDA, which may include one or more of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- mandatory recall or seizure of our products;
- administrative detention or banning of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or pre-market approval of new product versions;
- revocation of 510(k) clearance or pre-market approvals previously granted; and
- criminal prosecution and penalties.

#### *International Regulation*

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly.

#### **Other Healthcare Laws**

Although we currently do not have any products on the market, our current and future business activities are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to

mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal statute governing healthcare fraud statutes to a stricter standard. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the Affordable Care Act codifies case law that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, as stated above, many states have similar fraud and abuse laws that may be broader in scope and may apply regardless of payor.

Moreover, Section 6002 of the Affordable Care Act included new requirements for device manufacturers, among others, to report certain payments or "transfers of value" provided to physicians and teaching hospitals, and to report ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Section 6002 of PPACA includes in its reporting requirements a broad range of transfers of value including, but



not limited to, consulting fees, speaker honoraria, charitable contributions, research payments and grants. The Centers for Medicare & Medicaid Services, or CMS, issued its final rule implementing Section 6002 of the Affordable Care Act in February 2013, and required data collection commenced as of August 1, 2013. Manufacturers were required to report aggregated data for August through December of 2013 to CMS by March 31, 2014, and more detailed information regarding the specific payments and transfers of value in the second quarter of 2014. CMS will release the data on a public website by September 30, 2014. Failure to report could subject companies to significant financial penalties. Tracking and reporting the required payments and transfers of value may result in considerable expense and additional resources. Several states currently have similar laws and more states may enact similar legislation, some of which may be broader in scope. For example, certain states require the implementation of compliance programs, compliance with industry ethics codes, implementation of gift bans and spending limits, and/or reporting of gifts, compensation and other remuneration to healthcare professionals.

We also may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA. In addition to HIPAA criminal penalties, HITECH created four new tiers of civil and monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our future operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

### ***Coverage and Reimbursement***

Maintaining and growing sales of our product candidates, if approved, depends in large part on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. These third-party payors are increasingly limiting coverage and reducing reimbursement for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls and restrictions on coverage and reimbursement. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates

could reduce physician utilization of our products, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Hospitals, clinical laboratories and other healthcare provider customers that may purchase our product candidates, if approved, generally bill various third-party payors to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our product candidates. We currently expect that the majority of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payors, such as Medicare, general reimburse hospitals a single bundled payment that is based on the patients' diagnosis under a classification system known as the Medicare severity diagnosis-related groups, or MS-DRGs, classification for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. To the extent that our diagnostic tests will be performed in an outpatient setting, our product candidates may be eligible for separate payment using existing Current Procedural Terminology, or CPT, codes. Third-party payors may deny coverage, however, if they determine that our products are not cost-effective as determined by the payor, or is deemed by the third-party payor to be experimental or medically unnecessary. We are unable to predict at this time whether our product candidates, if approved, will be covered by third-party payors. Nor can we predict at this time the adequacy of payments, whether made separately in an outpatient setting or with a bundled payment amount in an inpatient setting. Our customers' access to adequate coverage and reimbursement for our product candidates by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our products, if approved, on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

### **Healthcare Reform**

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system seeking, among other things, to reduce healthcare costs that could affect our future results of operations as we begin to directly commercialize our products.

By way of example, in the United States, the Affordable Care Act was signed into law in March 2010, which is expected to substantially change the way healthcare is delivered and financed by both governmental and private insurers. Among other things, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States;
- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not

achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2014 unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressure.

## Research and Development

We have committed, and expect to commit, significant resources to developing new technologies and products, improving product performance and reliability and reducing costs. We have assembled an experienced research and development team with the scientific, engineering, software and process talent that we believe is required to successfully grow our business. As of March 31, 2014, our research and development team was comprised of 29 employees, of which nine hold a Ph.D. degree, eight hold a master's of science and 12 hold a bachelor's of science or equivalent. We are currently focused on several product candidates and enhancements utilizing our T2MR platform. We incurred research and development expenses of \$5.1 million for the three months ended March 31, 2014, \$14.9 million for the year ended December 31, 2013 and \$11.7 million for the year ended December 31, 2012. Research and development expenses represented 73.3% of our operating expenses for the three months ended March 31, 2014, 74.8% of our operating expenses for the year ended December 31, 2013 and 79.9% of our operating expenses for the year ended December 31, 2012. Major components of the research and development expenses were salaries and benefits, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

We continuously seek to improve T2MR, including improvements in its technology and accessibility. As we make improvements, we anticipate we will make available new and improved generations of our diagnostic instruments and panels. Our technology developmental efforts are focused on applying T2MR to additional potential applications in the *in vitro* diagnostic area. We are continuing our development of T2Bacteria and expect to initiate clinical trials for T2Bacteria in the second half of 2015. We believe that technical advantage is important to sustainable competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of our T2MR platform. We are dedicated to ongoing innovation to T2MR and expanding our pipeline of product candidates. Our goal is for T2MR to become a standard of care by providing technology that offers a rapid, sensitive and simple diagnostic alternative to existing methodologies for identifying both sepsis and impaired hemostasis, with a long-term objective of targeting the broader *in vitro* diagnostics market.

## Employees

As of March 31, 2014, we had 61 full-time permanent employees, of which 19 work in operations, 29 in research and development, nine in general and administrative and four in sales and marketing. In addition, we employ a number of temporary and contract employees. None of our employees is subject to a collective bargaining agreement.

**Facilities**

Our corporate headquarters is located in Lexington, Massachusetts, where we currently lease approximately 12,500 square feet of office space and 7,600 square feet of laboratory space. Our base rent under this lease, which expires in 2016, is \$0.6 million annually. We also lease approximately 6,500 square feet in Wilmington, Massachusetts for our manufacturing facility, under a lease that expires in 2015 for \$52,500 for base rent annually.

**Legal Proceedings**

We are not party to any material legal proceedings. From time to time, we may be subject to legal proceedings and claims in the ordinary course of business, including but not limited to matters involving employment or intellectual property.

**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the name and position of each of our executive officers and directors and their age as of March 31, 2014.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers</b>		
John McDonough	54	President and Chief Executive Officer and Director
Marc R. Jones	38	Chief Financial Officer
Sarah O. Kalil	55	Chief Operating Officer
Thomas J. Lowery, Ph.D.	35	Chief Scientific Officer
Michael A. Pfaller, M.D.	63	Chief Medical Officer
<b>Non-employee Directors</b>		
David B. Aronoff	49	Director
Joshua Bilenker, M.D.	42	Director
Thomas J. Carella	39	Director
Michael J. Cima, Ph.D.	54	Director
Alan Crane	50	Director
Stacy A. Feld	41	Director
Robert Langer, D. Sc.	65	Director
Stanley N. Lapidus	65	Director
Harry W. Wilcox	60	Director

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

**Executive Officers**

*John McDonough* has served as our President and Chief Executive Officer and a member of our board of directors since November 2007. From 2003 to 2007, Mr. McDonough held various positions at Cytoc Corporation, a company engaged in the design, development, manufacturing and marketing of clinical products that focus on women's health, where he ultimately served as President of Cytoc Development Corporation. Mr. McDonough received his B.S.B.A. from Stonehill College. Mr. McDonough's extensive management experience as a senior executive and his diagnostic company experience contributed to our board of directors' conclusion that he should serve as a director of our company.

*Marc R. Jones* has served as our Chief Financial Officer since April 2013. From January 2013 to March 2013, Mr. Jones was Chief Financial Officer of Crashlytics, a mobile device software company, until its acquisition by Twitter. From January 2012 to January 2013, Mr. Jones was Chief Financial Officer of Fluidnet, a medical device company. From June 2007 to August 2011, Mr. Jones was Chief Financial Officer of CHiL Semiconductor, a power management solutions company until its acquisition by International Rectifier. Mr. Jones received his M.S. in finance from Northeastern University and his B.S. in economics and finance from Southern New Hampshire University.

*Sarah O. Kalil* has served as our Chief Operating Officer since August 2013. From August 2010 to August 2013, Ms. Kalil was Chief Operating Officer of Interlace Medical, a medical device company, which was acquired by Hologic. From April 2009 to August 2010, Ms. Kalil was President and Chief Operating Officer of Boston Endo-Surgical Technologies, a medical device company.

From 2002 to 2009, Ms. Kalil was Operations Director of Innovend, a medical molding company. Ms. Kalil is a member of the Massachusetts General Hospital Cancer Patient and Family Advisory Council and on the board of the Pleiades Foundation. Ms. Kalil received her B.S. in engineering from the University of Vermont.

*Thomas J. Lowery, Ph.D.* has served as our Chief Scientific Officer since September 2013. Since joining our company in 2007, Dr. Lowery has held various technical leadership roles in the assay, methods, reagents and detector development programs. Dr. Lowery received his Ph.D. in chemistry from the University of California, Berkeley and his B.S. in biochemistry from Brigham Young University.

*Michael A. Pfaller, M.D.* has served as our Chief Medical Officer since March 2014. From 2005 until he joined our company, Dr. Pfaller was a consultant to JMI Laboratories, managing the *in vitro* testing of fungal and bacterial isolates. From 1983 to 2005, he was Clinical Director of Clinical Microbiology Laboratory at the University of Iowa, as well as Interim Director of Clinical Laboratories from 1984 to 1985. He currently serves as Co-Editor in Chief of the *American Society for Microbiology Manual of Clinical Microbiology*, 11<sup>th</sup> edition. Dr. Pfaller received his M.D. from the Washington University School of Medicine and his B.A. in chemistry from Linfield College.

## **Directors**

*David B. Aronoff* has served as a member of our board of directors since January 2014. Mr. Aronoff is a General Partner at Flybridge Capital Partners, a venture capital firm, a position he has held since 2005. From 1996 to 2005, Mr. Aronoff was a General Partner at Greylock Partners, a venture capital firm, and held management roles at Chipcom, an enterprise network equipment and software vendor, and AT&T Bell Laboratories. Mr. Aronoff received his B.S. in computer science from the University of Vermont, his M.S. in computer science from the University of Southern California and his M.B.A. from Harvard Business School. Mr. Aronoff's experience working in the venture capital industry and experience working with and serving on the boards of directors of numerous technology companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Joshua Bilenker, M.D.* has served as a member of our board of directors since 2011. Dr. Bilenker is Chief Executive Officer of Loxo Oncology, a biotechnology company focused on cancer therapeutics. He is also a partner at Aisling Capital, a position he has held since 2006. Prior to Aisling Capital, Dr. Bilenker was a Medical Officer in the Office of Oncology Drug Products at the FDA from 2004 to 2006. Dr. Bilenker received his M.D. from The Johns Hopkins School of Medicine and his B.A. from Princeton. Dr. Bilenker's extensive experience at the FDA and as an investor in life science companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Thomas J. Carella* has served as a member of our board of directors since March 2013. Mr. Carella is a Managing Director in the Merchant Banking Division of Goldman, Sachs & Co. and Global Head of the division's private equity activities in the healthcare sector, a position he has held since 2012. He previously served on the board of directors of KAR Auction Services, a provider of vehicle auction services in North America, from 2007 to 2013. Mr. Carella received his B.A. from Harvard College and his M.B.A. from Harvard Business School. Mr. Carella's management experience, including his extensive experience in business strategy for healthcare companies, contributed to our board of directors' conclusion that he should serve as a director of our company.

*Michael J. Cima, Ph.D.* is one of our founders and has served as a member of our board of directors since 2006. Since 1986, Dr. Cima has been a Professor of Materials Science and Engineering at Massachusetts Institute of Technology, or MIT, and he currently holds the David H. Koch Engineering Chair and an appointment at the Koch Institute for Integrative Cancer Research.

Dr. Cima received his B.S. in chemistry and his Ph.D. in chemical engineering, both from the University of California at Berkeley. Dr. Cima's extensive life science experience and knowledge of the diagnostics industry contributed to our board of directors' conclusion that he should serve as a director of our company.

*Alan Crane* has served as a member of our board of directors since November 2007. Mr. Crane joined Polaris Partners in 2002 and is a partner and entrepreneur focused on building and investing in healthcare companies. From 2006 to 2009, he served as Chief Executive Officer and co-founder of Cerulean Pharma, Inc., an oncology company. From 2002 to 2006, Mr. Crane served as Chief Executive Officer and, from 2001 to 2010, a director of Momenta Pharmaceuticals, a biotechnology company. Prior to Momenta, Mr. Crane held the position of Senior Vice President of Corporate Development at Millennium Pharmaceuticals, Inc. Mr. Crane received his M.B.A., M.A. and B.A. from Harvard University. Mr. Crane's breadth of management experience in the life science industry contributed to our board of directors' conclusion that he should serve as a director of our company.

*Stacy A. Feld* has served as a member of our board of directors since May 2010. Ms. Feld has been a Partner at Phycis Ventures, a venture capital firm, since 2009. From 2004 to 2008, Ms. Feld was Associate Director of Business Development at Genentech, Inc., a biotechnology company. Ms. Feld received her B.A. in sociology from the University of Pennsylvania and her J.D. from Vanderbilt Law School. Ms. Feld's experience working with and investing in life science companies and her experience in the venture capital industry contributed to our board of directors' conclusion that she should serve as a director of our company.

*Robert Langer, D. Sc.* is one of our founders and has served as a member of our board of directors since 2006. Dr. Langer has been an Institute Professor at MIT since 2005, and prior to that was an Assistant Professor at MIT since 1978. Dr. Langer served as a member of the FDA's SCIENCE Board, the FDA's highest advisory board, from 1995 until 2002 and as its Chairman from 2002 until 2009. Dr. Langer has received the National Medal of Science, National Medal of Technology and Innovation, Wolf Prize in Chemistry, Charles Stark Draper Prize, Albany Medical Center Prize in Medicine and Biomedical Research and the Lemelson-MIT prize. Dr. Langer was elected to the Institute of Medicine, the National Academy of Engineering and the National Academy of Sciences. Dr. Langer currently serves on the board of directors of Advanced Cell Technology and Bind Therapeutics. He previously served as a director of Momenta Pharmaceuticals from 2001 to 2009, Wyeth from 2004 to 2009, Fibrocell Science from 2010 to 2012 and Millipore Corporation from 2009 to 2010. Dr. Langer received his B.A. from Cornell University and his Sc.D. from MIT, both in chemical engineering. Dr. Langer's extensive experience with the FDA and in academic medicine, including as the recipient of numerous awards in recognition of his research, contributed to our board of directors' conclusion that he should serve as a director of our company.

*Stanley N. Lapidus* has served as a member of our board of directors since August 2008. Mr. Lapidus is President and Chief Executive Officer of SynapDx, an autism early detection company he founded in 2009. From 2003 to 2008, Mr. Lapidus was Chief Executive Officer of Helicos Biosciences, a life science company he co-founded in 2003. From 1995 to 2001, he was Chief Executive Officer of EXACT Sciences, a colorectal cancer diagnostics company he founded in 1995. From 1987 to 1994, he was Chief Executive Officer of Cytec Corp., a cervical cancer diagnostics company he founded in 1987. Mr. Lapidus holds academic appointments at Tufts University and MIT. He received his B.S. in engineering from Cooper Union. Mr. Lapidus' experience as a senior executive and his knowledge of life science companies contributed to our board of directors' conclusion that he should serve as a director of our company.

*Harry W. Wilcox* has served as a member of our board of directors since January 2011. Mr. Wilcox has been Chief Operating Officer and General Partner of Flagship Ventures, a venture

capital firm, since 2013. From 2006 to 2013, he was Chief Financial Officer and Partner of Flagship Ventures. From 2004 to 2006, he was Chief Financial Officer and Senior Vice President of Corporate Development of EXACT Sciences. Mr. Wilcox received his M.B.A. from Boston University and his B.S. in Finance from the University of Arizona. Mr. Wilcox's experience leading successful healthcare and technology companies, and his experience as a venture investor, contributed to our board of directors' conclusion that he should serve as a director of our company.

## **Board Composition and Election of Directors**

### ***Board Composition***

Our board of directors is currently comprised of ten members. The members of our board of directors were elected in compliance with the provisions of the voting agreement among us and our major stockholders. The voting agreement will terminate upon the closing of this offering, and we will have no further contractual obligations regarding the election of our directors. See "Certain Relationships and Related Person Transactions." Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal.

Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our first annual meeting of stockholders following this offering;
- the class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at the third annual meeting of stockholders following this offering.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

In selecting board members, our board may consider many factors, such as personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; experience as a board member or executive officer of another publicly held company; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; and diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience.



**Director Independence**

Applicable rules of the NASDAQ Stock Market, or NASDAQ, require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent, that compensation committee members meet a heightened independence test and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under applicable NASDAQ rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of the compensation committee, the board of directors must consider all factors specifically relevant to determining whether a director has a relationship with us which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by us to such director; and (ii) whether such director is affiliated with us, one of our subsidiaries or an affiliate of a subsidiary of ours.

Our board of directors has determined that \_\_\_\_\_ are "independent directors" as defined under applicable NASDAQ rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. McDonough is not an independent director under these rules because he is our Chief Executive Officer and \_\_\_\_\_ is not an independent director under these rules because of his consulting relationship with us. Please see the section of this prospectus titled "Certain Relationships and Related Person Transactions".

There are no family relationships among any of our directors or executive officers.

**Board Committees**

Our board has established three standing committees — audit, compensation, and nominating and corporate governance — each of which operates under a charter that has been approved by our board. Current copies of each committee's charter will be posted on the Corporate Governance section of our website at [www.t2biosystems.com](http://www.t2biosystems.com). The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

**Audit Committee**

Our audit committee is composed of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, with \_\_\_\_\_ serving as chairman of the committee. Our board of directors has determined that each member of the audit committee meets the independence requirements of the Sarbanes-Oxley Act of 2002, Rule 10A-3 under the Exchange Act and the applicable listing standards of NASDAQ. Our board of directors has determined that \_\_\_\_\_ and \_\_\_\_\_ are "audit committee

financial experts" within the meaning of the SEC regulations and applicable listing standards of NASDAQ. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and our code of business conduct and ethics;
- discussing our risk management policies;
- establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

**Compensation Committee**

Our compensation committee is composed of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act and an "outside director" as defined under Section 162(m) of the Internal Revenue Code of 1986, as amended. \_\_\_\_\_ will serve as chairman of the committee. Our board of directors has determined that each member of the compensation committee is "independent" as defined under the applicable listing standards of NASDAQ, including the standards specific to members of a compensation committee. The compensation committee's responsibilities include:

- determining our Chief Executive Officer's compensation;
- reviewing and approving, or making recommendations to our board with respect to, the compensation of our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," if applicable; and
- preparing the annual compensation committee report required by SEC rules, if applicable.

**Nominating and Corporate Governance Committee**

Our nominating and corporate governance committee is composed of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, with \_\_\_\_\_ serving as chairman of the committee. Our

board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined under the applicable listing standards of NASDAQ and SEC rules and regulations. The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become board members;
- recommending to our board the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and making recommendations to the board with respect to management succession planning;
- developing and recommending to the board corporate governance principles; and
- overseeing an annual evaluation of the board.

#### **Compensation Committee Interlocks and Insider Participation**

During 2013, the members of our compensation committee were \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_, each of whom is affiliated with certain of our principal stockholders. See "Certain Relationships and Related Person Transactions" for additional information on the securities acquired by such principal stockholders and related agreements such stockholders are party to with us. None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been employed by us. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see the section of this prospectus titled "Certain Relationships and Related Person Transactions".

#### **Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, our code of business conduct and ethics will be available on our website. We intend to disclose any amendments to the code, or any waivers of its requirements, as required by NASDAQ or SEC rules, on our website.

**EXECUTIVE AND DIRECTOR COMPENSATION**

This section discusses the material components of the executive compensation program offered to our named executive officers, or our NEOs, identified below. For 2013, our NEOs were:

- John McDonough, President and Chief Executive Officer;
- Marc R. Jones, Chief Financial Officer; and
- Sarah O. Kalil, Chief Operating Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

We are an "emerging growth company," within the meaning of the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

**Summary Compensation Table**

The following summarizes the total compensation awarded to, earned by or paid to our NEOs for their service to us in 2013:

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)<sup>(1)</sup></b>	<b>Option Awards (\$)<sup>(2)</sup></b>	<b>Non-Equity Incentive Plan Compensation (\$) (3)</b>	<b>Total (\$)</b>
John McDonough President and Chief Executive Officer	2013	350,000	310,942	66,000	726,942
Marc R. Jones Chief Financial Officer	2013	171,881	312,411	26,500	510,792
Sarah O. Kalil Chief Operating Officer	2013	89,789	311,780	26,500	428,069

- (1) Represents base salary earned during 2013. Mr. Jones joined our company on April 8, 2013, and Ms. Kalil joined our company on August 12, 2013.
- (2) Represents the aggregate grant date fair value of the option awards granted during 2013 computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For a description of the assumptions used in valuing these awards, see note 9 to our audited financial statements included elsewhere in this prospectus.
- (3) Represents awards earned under our annual cash incentive bonus program. For additional information regarding these amounts, see the section titled "Narrative Disclosure to Summary Compensation Table — Cash Bonuses" below.

**Narrative Disclosure to Summary Compensation Table**

The primary elements of compensation for our NEOs are base salary, cash bonuses and long-term equity-based compensation awards. The NEOs also participate in employee benefit plans and programs that we offer to our other full-time employees on the same basis.

### Base Salary

Our NEOs receive base salary to compensate them for the satisfactory performance of duties to our company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our NEOs have generally been set at levels deemed necessary to attract and retain individuals with superior talent. Base salaries for Mr. Jones and Ms. Kalil were negotiated in connection with their commencing employment with us during 2013. Mr. McDonough did not receive a base salary increase during 2013.

### Cash Bonuses

Each of our NEOs is eligible to participate in an annual cash incentive bonus program which provides participants with an opportunity to earn cash bonus awards based on individual and company performance. The target annual bonus levels for Mr. Jones and Ms. Kalil are 15% of their respective annual base salaries. Mr. McDonough's target annual bonus for 2013 was \$110,000.

Objectives for the 2013 annual bonus program were established in January 2013 by our compensation committee and generally related to attaining clinical, business development and financing milestones and publication, commercialization and operational goals.

In January 2014, our board of directors reviewed the performance of our NEOs against the applicable goals and, based on its evaluation and the recommendation of our compensation committee, determined to award each NEO an annual cash incentive bonus in the amount set forth in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

### Equity-Based Compensation

We generally offer stock options to our employees, including our NEOs, as the long-term incentive component of our compensation program. We typically grant options to employees when they commence employment with us and may thereafter grant additional options in the discretion of our board of directors. Our stock options generally allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant, as determined by the board of directors, and may be intended to qualify as "incentive stock options" under the Internal Revenue Code.

Our stock options typically vest as to 25% of the shares subject to the option on the first anniversary of the date of grant and in equal monthly installments over the ensuing 36 months, subject to the holder's continued employment with us. From time to time, our board of directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees. Stock options granted to our employees may be subject to accelerated vesting in certain circumstances, as described below in the sections titled "Employment Letter Agreements" and "Potential Payments upon a Change in Control".

We awarded stock options to our NEOs during 2013 in the following amounts:

<u>Named Executive Officer</u>	<u>2013 Options Granted (#)</u>
John McDonough	282,250
Marc R. Jones	282,250
Sarah O. Kalil	282,250

These options were granted with exercise prices equal to the fair market of our common stock on the date of grant, as determined by our board of directors. The options granted to Ms. Kalil and Mr. Jones vest as to 25% of the shares subject to the option on the first anniversary of their

respective employment commencement dates and in equal monthly installments over the ensuing 36 months. The option granted to Mr. McDonough vests as to 25% of the shares subject to the option on September 25, 2014 and in equal monthly installments over the ensuing 36 months.

In connection with this offering, we intend to adopt a new incentive plan to facilitate the grant of cash and equity incentives to our directors, employees and consultants and to enable our company to obtain and retain the services of these individuals. Additional information about our new incentive plan is provided in the section titled "2014 Incentive Award Plan" below.

*Retirement, Health, Welfare and Additional Benefits*

Our NEOs are eligible to participate in our employee benefit plans and programs, including medical and dental benefits, flexible spending accounts and short- and long-term disability and life insurance, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans. Our NEOs are also eligible to participate in a tax-qualified 401(k) defined contribution plan to the same extent as all of our other full-time employees. Currently, we do not match contributions made by participants in the 401(k) plan or make other contributions to participant accounts.

**Outstanding Equity Awards at 2013 Fiscal Year-End**

The following table summarizes the outstanding equity awards held by our NEOs as of December 31, 2013.

Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Option Awards		
			Number of Securities Underlying Unexercised Options Unexercisable (#) <sup>(1)</sup>	Option Exercise Price (\$)	Option Expiration Date
John McDonough	9/25/2013	—	282,250	1.89	10/24/2023
	1/17/2012	158,484	172,266	1.44	1/17/2022
	6/24/2010	210,559	30,082	1.15	9/14/2020
	2/27/2009	19,940	—	0.68	2/27/2019
	1/16/2009	79,571	—	0.68	1/16/2019
Marc R. Jones	4/8/2013	—	282,250	1.89	6/25/2023
Sarah O. Kalil	8/12/2013	—	282,250	1.89	9/25/2023

(1) All unvested options vest as to 25% of the total shares subject to the option on the first anniversary of the vesting commencement date and in equal monthly installments over the ensuing 36 months, subject to the holder's continued employment with us through the applicable vesting date and potential accelerated vesting as described in the sections titled "Employment Letter Agreements" and "Potential Payments upon a Change in Control" below.

**Employment Letter Agreements**

We have entered into employment letter agreements with each of our NEOs. Certain key terms of these agreements are described below.

**John McDonough**

We entered into an employment letter agreement with Mr. McDonough on March 14, 2008. This agreement entitles Mr. McDonough to receive an initial annual base salary of \$300,000, subject to periodic increases at the discretion of the board of directors, and an annual bonus opportunity of up to \$75,000, with the amount of any such bonus based primarily on the overall performance of our company, measured against goals that are mutually agreed between Mr. McDonough and our compensation committee early in each applicable year. If Mr. McDonough's employment is terminated without cause (other than in connection with a change in control), he is entitled to receive six months of base salary continuation and a lump-sum payment in an amount equal to 50% of the maximum annual bonus which he could have earned for the year of termination. If Mr. McDonough's employment is terminated by us without cause within the three months preceding or the 12 months following a change in control or if Mr. McDonough resigns his employment for good reason within the 12 months following a change in control, he will be entitled to receive 12 months of base salary continuation and a lump-sum payment in an amount equal to 50% of the maximum annual bonus which he could have earned for the year of termination.

Mr. McDonough's employment letter agreement also contains restrictive covenants pursuant to which he has agreed to refrain from competing with us or soliciting our customers or prospective customers for one year following his termination of employment.

**Marc R. Jones**

We entered into an employment letter agreement with Mr. Jones on March 8, 2013. This agreement entitles him to an initial annual base salary of \$235,000 and an annual bonus up to 15% of his annual base salary. This agreement further provides that if a change in control occurs after which Mr. Jones is no longer employed by the surviving entity following the change in control, (i) he will be entitled to receive six months of base salary continuation and six months of company paid healthcare continuation pursuant to COBRA and (ii) 50% of the unvested stock options held by him will immediately vest if the change in control occurs within 12 months of his employment commencement date or 100% of the unvested stock options held by him will immediately vest if the change in control occurs more than 12 months following his employment commencement date.

Mr. Jones has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which he has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of his employment.

**Sarah O. Kalil**

We entered into employment letter agreement with Ms. Kalil on July 19, 2013. This agreement entitles her to an initial annual base salary of \$230,000 and an annual bonus up to 15% of her annual base salary. This agreement further provides that if a change in control occurs and Ms. Kalil is no longer employed by the surviving entity following the change in control, 50% of the unvested stock options held by her will immediately vest if the change in control occurs within 12 months of her employment commencement date or 100% of the unvested stock options held by her will immediately vest if the change in control occurs more than 12 months following her employment commencement date.

Ms. Kalil has also entered into a non-compete, non-disclosure and invention assignment agreement with us pursuant to which she has agreed to refrain from disclosing our confidential information indefinitely and from competing with us or soliciting our employees or consultants for 12 months following termination of her employment.

## **Potential Payments upon a Change in Control**

As described above, under the terms of their employment letter agreements, Mr. McDonough, Mr. Jones and Ms. Kalil may become entitled to certain payments or benefits for certain terminations of employment that occur in connection with a change in control.

The agreements governing Mr. McDonough's unvested stock options provide for full accelerated vesting if his employment is terminated without cause or if he resigns for good reason within 12 months following a change in control. Mr. McDonough also participates in the management incentive plan described in the section titled "Transaction Bonus Plan" below.

## **Transaction Bonus Plan**

Our board of directors has approved a Management Incentive Plan, which we refer to as the MIP, under which certain key employees, including Mr. McDonough, may become eligible to receive certain cash payments upon a change in control of our company on or before December 31, 2014. Payments under the MIP are generally equal to a specified percentage of the change in control transaction proceeds above a certain threshold. To receive awards under the MIP, the participant must continue to be employed by our company at the time of the change in control transaction or have been terminated without cause within three months prior to the change in control transaction. We do not expect to maintain the MIP following the consummation of this offering.

## **Incentive Plans**

### ***2014 Incentive Award Plan***

In connection with this offering, we intend to adopt a 2014 Incentive Award Plan, or the 2014 Plan, subject to approval by our stockholders, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2014 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2014 Plan and, accordingly, this summary is subject to change.

### ***Eligibility and Administration***

Our employees, consultants and directors, and the employees, consultants and directors of our subsidiaries, will be eligible to receive awards under the 2014 Plan. Following our initial public offering, the 2014 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under Section 16 of the Exchange Act and stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2014 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2014 Plan, including any vesting and vesting acceleration conditions.

### ***Limitation on Awards and Shares Available***

An aggregate of \_\_\_\_\_ shares of our common stock will initially be available for issuance under awards granted pursuant to the 2014 Plan. The number of shares initially available for issuance will be increased by (i) the number of shares represented by awards outstanding under our Amended and Restated 2006 Employee, Director and Consultant Stock Plan, or the 2006 Plan, that are forfeited, lapse unexercised or are settled in cash and which following the effective



date of the 2014 Plan are not issued under the 2006 Plan and (ii) an annual increase on January 1 of each calendar year beginning in 2015 and ending in 2024, equal to the lesser of (A) shares, (B) % of the shares of common stock outstanding (on an as converted basis) on the final day of the immediately preceding calendar year and (C) such smaller number of shares as determined by our board of directors. No more than shares of common stock may be issued upon the exercise of incentive stock options. Shares issued under the 2014 Plan may be authorized but unissued shares, or shares purchased in the open market.

If an award under the 2014 Plan is forfeited, expires or is settled for cash, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2014 Plan. Awards granted under the 2014 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2014 Plan. The maximum number of shares of our common stock that may be subject to one or more awards granted to any non-employee director for services as a director pursuant to the 2014 Plan during any calendar year will be , provided that a non-employee director may be granted awards under the 2014 Plan for services as a director for any one year in excess of such amount if the total awards granted to the director under the 2014 Plan for services as a director in the year do not have a grant date fair value, as determined in accordance with FASB ASC Topic 718 (or any successor thereto) in excess of \$ .

#### Awards

The 2014 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, stock payments, restricted stock units, or RSUs, performance shares, other incentive awards, stock appreciation rights, or SARs, and cash awards. No determination has been made as to the types or amounts of awards that will be granted to specific individuals pursuant to the 2014 Plan. Certain awards under the 2014 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Internal Revenue Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2014 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- **Stock Options.** Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Internal Revenue Code are satisfied. The exercise price of a stock option generally will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and other conditions.
- **SARs.** SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will generally not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute

SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and other conditions.

- *Restricted Stock, RSUs and Performance Shares.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Performance shares are contractual rights to receive a range of shares of our common stock in the future based on the attainment of specified performance goals, in addition to other conditions which may apply to these awards. Conditions applicable to restricted stock, RSUs and performance shares may be based on continuing service, the attainment of performance goals and such other conditions as the plan administrator may determine.
- *Stock Payments, Other Incentive Awards and Cash Awards.* Stock payments are awards of fully vested shares of our common stock that may, but need not, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. Other incentive awards are awards other than those enumerated in this summary that are denominated in, linked to or derived from shares of our common stock or value metrics related to our shares, and may remain forfeitable unless and until specified conditions are met. Cash awards are cash incentive bonuses subject to performance goals.
- *Dividend Equivalents.* Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards. Dividend equivalents are credited as of dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

#### *Performance Awards*

Performance awards include any of the foregoing awards that are granted subject to vesting or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include but are not limited to: (i) net earnings (either before or after one or more of (A) interest, (B) taxes, (C) depreciation and (D) amortization); (ii) gross or net sales or revenue; (iii) net income (either before or after taxes); (iv) adjusted net income; (v) operating earnings or profit; (vi) cash flow (including, but not limited to, operating cash flow and free cash flow); (vii) return on assets; (viii) return on capital; (ix) return on stockholders' equity; (x) total stockholder return; (xi) return on sales; (xii) gross or net profit or operating margin; (xiii) costs; (xiv) expenses; (xv) working capital; (xvi) earnings per share; (xvii) adjusted earnings per share; (xviii) price per share; (xix) regulatory body approval for commercialization of a product; (xx) implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; (xxi) market share; (xxii) economic value; (xxiii) revenue and (xxiv) revenue growth.

#### *Certain Transactions*

The plan administrator has broad discretion to take action under the 2014 Plan, as well as to make adjustments to the terms and conditions of existing and future awards, to prevent the dilution

or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2014 Plan and outstanding awards. In the event of a change of control of our company (as defined in the 2014 Plan) or a reorganization, merger, liquidation or similar corporate transaction, or any other unusual or non-recurring transactions affecting us or our financial statements, or a change in applicable accounting principles or law, the plan administrator may (i) terminate awards for cash or replace awards with other property or rights; (ii) provide that outstanding awards will be assumed or substituted by a successor entity; (iii) adjust the number and types of shares subject to outstanding awards; (iv) provide that outstanding awards will be fully vested and exercisable; or (v) terminate any outstanding awards. Individual award agreements may provide for additional accelerated vesting and payment provisions.

*Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments*

The plan administrator may modify award terms, establish subplans and adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2014 Plan are generally non-transferable prior to vesting, and are exercisable only by the participant. With regard to tax withholding, exercise price and purchase price obligations arising in connection with awards under the 2014 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable.

*Plan Amendment and Termination*

Our board of directors may amend or terminate the 2014 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2014 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its price per share. No award may be granted pursuant to the 2014 Plan after the tenth anniversary of the date on which our board of directors adopts the 2014 Plan.

***Amended and Restated 2006 Employee, Director and Consultant Stock Plan***

Our board of directors and stockholders have approved the 2006 Plan, under which we may grant stock options and other stock-based awards to employees, directors and consultants of our company or its affiliates. We have reserved a total of 4,706,890 shares of our common stock for issuance under the 2006 Plan.

Following the effectiveness of the 2014 Plan, we will not make any further grants under the 2006 Plan. However, the 2006 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. As discussed above, we anticipate that shares of our common stock subject to awards granted under the 2006 Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2014 Plan are not issued under the 2006 Plan will be available for issuance under the 2014 Plan.

### *Administration*

Our board of directors administers the 2006 Plan and has the authority to determine recipients of awards and the terms of awards granted under the 2006 Plan, to interpret the 2006 Plan and awards outstanding thereunder, to buy out awards outstanding under the 2006 Plan for a payment in cash or shares of our common stock or cancel any such awards and substitute other awards therefor, including awards with an exercise price per share that is less than the exercise price per share of the replaced award, and to make changes to awards outstanding under the 2006 Plan, provided that such changes may not impair a participant's rights under the plan without the participant's consent. All such powers are exercised in the context of preserving the tax status of options granted under the plan that are intended to be ISOs. The board of directors may delegate its authority under the 2006 Plan to a committee. Following the effectiveness of this offering, our board of directors may delegate its general administrative authority under the 2006 Plan to its compensation committee.

### *Types of Awards*

The 2006 Plan provides for the grant of non-qualified and incentive stock options, stock grants and other stock-based awards to employees, directors and consultants of our company or its affiliates. As of the date of this prospectus, awards of incentive stock options and non-qualified stock options are outstanding under the 2006 Plan.

### *Certain Transactions*

If certain changes are made in, or events occur with respect to, our common stock, the 2006 Plan and outstanding awards will be appropriately adjusted in the class, number and, as applicable, exercise price of securities as determined by the plan administrator. In the event of certain corporate transactions of our company, including a consolidation, merger, sale of all or substantially all of our assets or a liquidation, our board of directors (or the board of a surviving entity assuming our company's obligations under the 2006 Plan) may make appropriate provision for the continuation or equitable substitution of outstanding awards, provide for the assumption or replacement of outstanding stock options, terminate awards for a cash payment equal to the excess of the fair market value of the underlying shares over the exercise or purchase price of the applicable award or provide that all stock options will terminate if not exercised within a specified number of days. The vesting and exercisability of awards may accelerate in connection with such a transaction, either by action of the plan administrator or under the terms of the applicable award agreements.

### *Amendment and Termination*

The plan administrator may terminate, modify or amend the 2006 Plan from time to time, provided that any amendment or modification may not adversely affect a participant's rights under the 2006 Plan without the participant's consent. Any amendment the plan administrator determines is of a scope that requires stockholder approval will be subject to approval by our stockholders. The 2006 Plan will terminate on July 20, 2016, if not earlier terminated by the board of directors or our stockholders.

### **Director Compensation**

We have not historically provided annual cash retainers or other compensation to our directors but have, from time to time, granted stock option awards to certain directors as compensation for their service on our board. Mr. McDonough, our President and Chief Executive Officer, also serves

as a member of our board of directors but does not receive any additional compensation for providing these services.

The following table provides information regarding the compensation earned by our non-employee directors during the year ended December 31, 2013.

<b>Name</b>	<b>Option Awards (\$) (1)</b>	<b>All Other Compensation (\$)(2)</b>	<b>Total (\$)</b>
David B. Aronoff	—	—	—
Joshua Bilenker, M.D.	—	—	—
Thomas J. Carella	—	—	—
Michael J. Cima, Ph.D.	108,374	40,000	148,374
Alan Crane	—	—	—
Stacy A. Feld	—	—	—
Robert Langer, D. Sc.	108,374	40,000	148,374
Stanley N. Lapidus	27,622	—	27,622
Harry W. Wilcox	—	—	—

- (1) Represents the aggregate grant date fair value of the option awards granted during 2013 computed in accordance with FASB ASC Topic 719 excluding the effect of estimated forfeitures. For a description of the assumptions used in valuing these awards, see note 9 to our audited financial statements included elsewhere in this prospectus. As of December 31, 2013, Drs. Langer and Cima each held options to purchase a total of 200,000 shares of our common stock, and Mr. Lapidus held options to purchase 175,000 shares of our common stock. No other non-employee director held any option awards and none of our non-employee directors held any stock awards as of December 31, 2013.
- (2) Represents consulting fees earned by Drs. Langer and Cima for 2013 under their respective consulting agreements with our company. See "Certain Relationships and Related Person Transactions — Consulting Agreements" for a description of these agreements.

**CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS**

The following includes a summary of transactions since January 1, 2011 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation". We also describe below certain other transactions with our directors, executive officers and stockholders.

**Preferred Stock Financings****Series D Preferred Stock Financing**

In August 2011, we sold 5,054,945 shares of series D preferred stock to new and existing investors at a price of \$4.55 per share, resulting in proceeds of \$23.0 million.

**Series E Preferred Stock Financing**

In March 2013, we sold 6,930,967 shares of series E preferred stock to new and existing investors at a price of \$5.7712 per share, resulting in proceeds of \$40.0 million.

The following table sets forth the aggregate number of these securities acquired by the listed holders of more than 5% of our capital stock or their affiliated entities and one member of our board of directors. Each share of our preferred stock identified in the following table will convert into one share of common stock upon the closing of this offering.

<b>Participant</b>	<b>Series D</b>	<b>Series E</b>
<b>5% or Greater Stockholders<sup>(1)</sup></b>		
Broad Street Principal Investments, LLC	—	4,331,858
Polaris Partners	629,852	631,133
Flagship Ventures Fund	629,851	631,133
Aisling Capital III, L.P.	2,967,033	549,851
Flybridge Capital Partners	369,792	370,544
Physic Ventures	247,934	248,437
<b>Member of our Board of Directors<sup>(2)</sup></b>		
Michael Cima, Ph.D.	—	4,332

(1) Additional details regarding these stockholders and their equity holdings are provided under the caption "Principal Stockholders".

(2) Additional details regarding this member of our board of directors and his equity holdings are provided under the caption "Principal Stockholders".

The following directors are associated with our 5% or greater stockholders:

<b>Director</b>	<b>Principal Stockholder</b>
Thomas J. Carella	Broad Street Principal Investments, LLC
Alan Crane	Polaris Partners
Harry W. Wilcox	Flagship Ventures Fund
Joshua Bilenker, M.D.	Aisling Capital III, L.P.
David B. Aronoff	Flybridge Capital Partners
Stacy A. Feld	Physic Ventures

### **Employment Letter Agreements**

We have entered into employment letter agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see "Executive and Director Compensation — Employment Letter Agreements".

### **Investors' Rights Agreement**

In connection with our series E preferred stock financing, we entered into a fourth amended and restated investors' rights agreement with holders of our preferred stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors. The investors' rights agreement, among other things, grants these stockholders specified registration rights with respect to shares of our common stock, including shares of common stock issued or issuable upon conversion of the shares of preferred stock held by them. For more information regarding the registration rights provided in these agreements, please refer to the section entitled "Description of Capital Stock — Registration Rights".

### **Consulting Agreements**

In June 2006, we entered into consulting agreements with Drs. Langer and Cima, pursuant to which we agreed to pay Drs. Langer and Cima quarterly compensation for their services to our company. The annual compensation increased to \$40,000 each upon the achievement of raising \$20.0 million in equity financing, license transaction payments, corporate research/partnership or licensing deals of such value, grants of such value, sales of such value or any combination of the foregoing. The total compensation expense for the years ended December 31, 2013 and 2012 and from April 27, 2006 (inception) to December 31, 2013 was \$80,000, \$80,000 and \$385,000, respectively. For more information regarding the compensation paid to Drs. Langer and Cima, see "Executive and Director Compensation — Director Compensation".

### **Indemnification Agreements**

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

### **Stock Option Grants to Executive Officers and Directors**

We have granted stock options to our executive officers and certain of our directors as more fully described in the section entitled "Executive and Director Compensation".

### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person

has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee considers all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.



## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of March 31, 2014, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on \_\_\_\_\_ shares of common stock outstanding as of March 31, 2014, assuming the conversion of all outstanding shares of preferred stock into common stock and the net exercise of all outstanding warrants into common stock, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options held by such person that are currently exercisable or will become exercisable within 60 days of March 31, 2014 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 101 Hartwell Avenue, Lexington, Massachusetts. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Prior to Offering	After Offering
<b>5% or Greater Stockholders</b>			
Entities affiliated with Broad Street Principal Investments, LLC <sup>(1)</sup>	4,331,858		
Entities affiliated with Polaris Partners <sup>(2)</sup>	4,036,773		
Entities affiliated with Flagship Ventures Fund <sup>(3)</sup>	4,036,772		
Aisling Capital III, L.P. <sup>(4)</sup>	3,516,884		
Entities affiliated with Flybridge Capital Partners <sup>(5)</sup>	2,370,029		
Physic Ventures, L.P. <sup>(6)</sup>	1,589,028		
<b>Named Executive Officers and Directors</b>			
John McDonough <sup>(7)</sup>	780,837		
Marc R. Jones <sup>(8)</sup>	76,442		
Sarah O. Kalil	—		
David B. Aronoff <sup>(5)</sup>	2,370,029		
Joshua Bilenker, M.D. <sup>(4)</sup>	3,516,884		
Thomas J. Carella <sup>(1)</sup>	4,331,858		
Michael J. Cima, Ph.D. <sup>(9)</sup>	426,554		
Alan Crane <sup>(2)</sup>	4,036,773		
Stacy A. Feld <sup>(6)</sup>	1,589,028		
Robert Langer, D. Sc. <sup>(10)</sup>	422,222		
Stanley N. Lapidus <sup>(11)</sup>	130,207		
Harry W. Wilcox <sup>(3)</sup>	4,036,772		
All executive officers and directors as a group (14 persons) <sup>(12)</sup>	21,880,165		

\* Less than 1%.

(1) Includes (a) 3,638,761 shares of common stock held by Broad Street Principal Investments, LLC, (b) 537,150 shares of common stock held by Bridge Street 2013 Holdings, L.P. and (c) 155,947 shares of common stock held by MBD 2013 Holdings, L.P., collectively the GS Entities. The GS Entities, of which affiliates of the Goldman Sachs Group, Inc. are the general partner, managing general partner or investment manager, share voting and investment power with certain of its respective affiliates. Mr. Thomas J. Carella is a Managing Director of Goldman, Sachs & Co. and may be deemed to have beneficial ownership of the shares held by the GS Entities. The Goldman Sachs Group, Inc., Goldman, Sachs & Co. and Mr. Carella each disclaim beneficial ownership of the shares held directly or indirectly by the GS Entities, except to the extent of its pecuniary interest therein, if any. The address of the GS Entities, the Goldman Sachs Group, Inc., Goldman, Sachs & Co. and Mr. Carella is c/o The Goldman Sachs Group, 200 West Street, New York, New York 10282.

(2) Includes (a) 3,895,222 shares of common stock held by Polaris Venture Partners V, L.P., or Polaris V, (b) 75,917 shares of common stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., or Polaris EFund V, (c) 38,952 shares of common stock held by Polaris Venture Partners Special Founders' Fund V, L.P., or Polaris SFFund V, and (d) 26,682 shares of common stock held by Polaris Venture Partners Founders' Fund V, L.P., or Polaris FFund, collectively, the Funds. Each of the Funds has the sole voting and investment power with respect to the shares directly held by it. The general partner of each of the Funds is Polaris

Venture Management Co. V, LLC, or Polaris Management. Polaris Management may be deemed to have sole voting and investment power with respect to the shares held by the Funds and disclaims beneficial ownership of all the shares held by the Funds except to the extent of its proportionate pecuniary interest therein. The members of North Star Venture Management 2000, LLC, Terrence McGuire and Jonathan Flint, collectively the Management Members, are also members of Polaris Management, and as members of the general partner, they may be deemed to share voting and investment power over the shares held by the Funds. The Management Members disclaim beneficial ownership of such shares, except to the extent of their proportionate pecuniary interest therein. Alan Crane, one of our directors, is a partner of Polaris Management. Mr. Crane disclaims beneficial ownership of all the shares held by the Funds except to the extent of his proportionate pecuniary interest therein. The mailing address of the beneficial owner is c/o Polaris Partners, 1000 Winter Street, Suite 3350, Waltham, MA 02451.

- (3) Includes (a) 2,775,788 shares of common stock held by Flagship Ventures Fund 2004, L.P. and (b) 1,260,984 shares of common stock held by Flagship Ventures Fund IV, L.P., or, collectively, Flagship. The general partner of Flagship is Flagship Ventures General Partner LLC, or Flagship LLC. Harry W. Wilcox, one of our directors, is a Member of Flagship LLC. As a result, each of Flagship LLC and Mr. Wilcox may be deemed to possess voting and investment control over, and may be deemed to have indirect beneficial ownership with respect to, all shares held by Flagship. Neither Flagship LLC nor Mr. Wilcox owns directly any of the shares. Each of Flagship LLC and Mr. Wilcox disclaims beneficial ownership of the shares held by Flagship except to the extent of their pecuniary interest therein. The mailing address of the beneficial owner is One Memorial Drive, 7th Floor, Cambridge, MA 02142.
- (4) The general partner of Aisling Capital III, L.P., or AC III, is Aisling Capital Partners III, L.P., or ACP III. The investment manager of ACP III is Aisling Capital, LLC, or Aisling Capital. Joshua Bilenker, M.D., a member of our board of directors, is a managing member of Aisling Capital. Each of Aisling Capital, ACP III and Dr. Bilenker may be deemed to beneficially own the shares held by AC III. Each of Aisling Capital, ACP III and Dr. Bilenker disclaims any beneficial ownership of the shares owned by AC III except to the extent of their pecuniary interest in such entity. The mailing address of the beneficial owner is 888 Seventh Avenue, 29<sup>th</sup> Floor, New York, NY 10016.
- (5) Includes (a) 2,279,720 shares of common stock held by Flybridge Capital Partners II, L.P., or FCP II, and (b) 90,309 shares of common stock held by Flybridge Capital Partners I, L.P., or FCP I, collectively the Flybridge Entities. The general partner of the Flybridge Entities is Flybridge Capital Partners GP I, LLC and Flybridge Capital Partners GP II, LLC (collectively the "Flybridge General Partners"). David Aronoff, one of our directors, is a managing member of the Flybridge General Partners. As a result, each of the Flybridge General Partners and Mr. Aronoff may be deemed to possess voting and investment control over, and may be deemed to have indirect beneficial ownership with respect to, all shares held by the Flybridge Entities. Each of Flybridge General Partners and Mr. Aronoff disclaims any beneficial ownership of the shares held by the Flybridge Entities except to the extent of their pecuniary interest therein. The mailing address of the beneficial owner is c/o Flybridge Capital Partners, 500 Boylston Street, 18th Floor, Boston, MA 02116.
- (6) Stacy A. Feld, one of our directors, is a partner of Physic Ventures. As a result, Ms. Feld may be deemed to beneficially own the shares held by Physic Ventures. Ms. Feld disclaims any beneficial ownership of the shares owned by Physic Ventures except to the extent of her pecuniary interest in such entity. The mailing address of the beneficial owner is c/o Physic Ventures, 548 Market Street #70998, San Francisco, CA 94104.

- (7) Includes (a) 263,098 shares of common stock and (b) 517,739 shares which Mr. McDonough has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.
- (8) Consists of 76,442 shares which Mr. Jones has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.
- (9) Includes (a) 304,332 shares of common stock and (b) 122,222 shares which Dr. Cima has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.
- (10) Includes (a) 300,000 shares of common stock and (b) 122,222 shares which Dr. Langer has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.
- (11) Consists of 130,207 shares which Mr. Lapidus has the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.
- (12) Includes (a) 20,748,774 shares of common stock and (b) 1,131,391 shares of common stock which our directors and executive officers as a group have the right to acquire pursuant to outstanding stock options which are or will be immediately exercisable within 60 days of March 31, 2014.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description summarizes some of the terms of our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our outstanding warrants, the investors' rights agreement and of the General Corporation Law of the State of Delaware. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, amended and restated bylaws, warrants and investors' rights agreement, copies of which have been or will be filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the General Corporation Law of the State of Delaware. The description of our common stock and preferred stock reflects changes to our capital structure that will occur upon the closing of this offering.

Following the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.001 per share.

As of March 31, 2014, we had issued and outstanding:

- 2,400,422 shares of our common stock held of record by 28 stockholders;
- 282,849 shares of our series A-1 preferred stock that are convertible into 282,849 shares of our common stock as of such date;
- 1,703,959 shares of our series A-2 preferred stock that are convertible into 1,703,959 shares of our common stock as of such date;
- 3,249,877 shares of our series B preferred stock that are convertible into 3,249,877 shares of our common stock as of such date;
- 4,055,125 shares of our series C preferred stock that are convertible into 4,055,125 shares of our common stock as of such date;
- 5,054,945 shares of our series D preferred stock that are convertible into 5,054,945 shares of our common stock as of such date; and
- 6,930,967 shares of our series E preferred stock that are convertible into 6,930,967 shares of our common stock as of such date.

In connection with this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 21,277,722 shares of our common stock.

### Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and amended and restated bylaws also will provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to

adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. See below under "— Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws — Amendment of Charter Provisions". Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

#### **Preferred Stock**

Under the terms of our restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

#### **Stock Options**

As of March 31, 2014, we had outstanding stock options to purchase an aggregate of 3,880,504 shares of our common stock under our 2006 Plan.

#### **Warrants**

In connection with the Loan and Security Agreement dated August 20, 2007, as amended on June 26, 2009 and June 25, 2012, with Silicon Valley Bank, or SVB, we issued warrants to SVB that are exercisable for 13,769 shares of series A-2 preferred stock, 9,036 shares of our series B preferred stock and 19,780 shares of series D preferred stock at an exercise price per share of \$2.9050, \$3.3232 and \$4.55, respectively. If unexercised, these warrants will expire upon the closing of this offering.

In September 2008, we issued warrants to In-Q-Tel, Inc. that are immediately exercisable for 174,530 and 3,612 shares of our series B preferred stock, at an exercise price per share of \$3.3232 and \$4.65, respectively. If unexercised, these warrants will expire upon the closing of this offering.

In May 2011, in connection with a Security Agreement dated May 9, 2011 with Massachusetts Development Finance Agency, or MDF, we issued a warrant to MDF that is immediately exercisable for 30,000 shares of our series C preferred stock, at an exercise price per share of \$3.6608. Immediately prior to the closing of this offering, this warrant will automatically convert into shares of series C preferred stock pursuant to a cashless net exercise provision, as described below.

Each of the above warrants has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of the applicable series of our preferred stock based on the fair market value of such preferred stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. These warrants also contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations.

#### **Registration Rights**

As of March 31, 2014, upon the closing of this offering, holders of \_\_\_\_\_ shares of our common stock, including shares issuable upon the exercise of warrants, or their transferees, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to a fourth amended and restated investors' rights agreement by and among us and certain of our stockholders, until such shares can otherwise be sold without restriction under Rule 144, or until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

#### ***Demand Registration Rights***

If at any time beginning 180 days after the closing date of this offering the holders of at least 30% of the registrable securities request in writing that we effect a registration of an aggregate amount of at least \$10,000,000 with respect to all or part of such registrable securities then outstanding, we may be required to register their shares. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

#### ***Piggyback Registration Rights***

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

#### ***Form S-3 Registration Rights***

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of registrable securities request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$3,000,000, we will be required to effect such registration; provided, however,

that we will not be required to effect such a registration if, within a given six-month period, we have already effected one registration on Form S-3 for the holders of registrable securities.

### **Expenses**

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders and blue sky fees and expenses.

### **Termination of Registration Rights**

The registration rights terminate upon the earlier of five years after the effective date of the registration statement of which this prospectus is a part, or, with respect to the registration rights of an individual holder, when the holder can sell all of such holder's registrable securities in a 90-day period without restriction under Rule 144 of the Securities Act.

### **Waiver of Registration Rights**

Holders of a majority of the shares of common stock entitled to registration rights under the fourth amended and restated investors rights agreement have waived the right of all of such holders to exercise such registration rights for a period of not less than 180 days after the date of this prospectus.

### **Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

Some provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### **Undesignated Preferred Stock**

The ability of our board of directors, without action by the stockholders, to issue up to \_\_\_\_\_ shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.



**Stockholder Meetings**

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

**Requirements for Advance Notification of Stockholder Nominations and Proposals**

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

**Elimination of Stockholder Action by Written Consent**

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

**Staggered Board**

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see "Management — Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

**Removal of Directors**

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

**Stockholders Not Entitled to Cumulative Voting**

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

**Delaware Anti-Takeover Statute**

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a

financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

#### **Choice of Forum**

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

#### **Amendment of Charter Provisions**

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be .

#### **Listing**

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "TTOO".

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of \_\_\_\_\_ shares of common stock, assuming the issuance of \_\_\_\_\_ shares of common stock offered by us in this offering, the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock, the issuance of \_\_\_\_\_ shares of common stock upon the net exercise of all outstanding warrants, and no exercise of options after March 31, 2014. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining \_\_\_\_\_ shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately \_\_\_\_\_ shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the 3,880,504 shares of our common stock that were subject to stock options outstanding as of March 31, 2014, options to purchase 1,641,933 shares of common stock were vested as of March 31, 2014 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

### Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of Goldman, Sachs & Co. and Morgan Stanley & Co. LLC, on behalf of the underwriters, we and they will not, subject to limited exceptions described below, during the period ending 180 days after the date of this prospectus:

- offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, or publicly disclose an intention to take any such actions with respect to, any shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or hereinafter acquired, owned directly or indirectly; or
- request, make any demand for or exercise any right with respect to, the registration of any of our common stock or any security convertible into or exercisable or exchangeable for our common stock;

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

In the case of our officers, directors and stockholders, these lock-up restrictions are subject to certain exceptions, including transfers (i) made as bona fide gifts; (ii) for the primary purpose of satisfying exercise price and/or tax withholding obligations upon the vesting or exercise of an option

or other award granted under a stock incentive plan or stock purchase plan of the Company; (iii) acquired in open market transactions; (iv) as part of a distribution, transfer or disposition without consideration to a holder's limited or general partners; and (v) in connection with the establishment of a trading plan pursuant to 10b5-1 under the Exchange Act.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

#### **Rule 144**

##### ***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; or
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and NASDAQ concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

##### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

#### **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in

reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

### **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

### **Registration Rights**

Upon the closing of this offering, the holders of \_\_\_\_\_ shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock upon the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement, except for shares purchased by affiliates. See "Description of Capital Stock — Registration Rights" for additional information. Holders of a majority of the shares of common stock entitled to such registration rights have waived the right of all of such holders to exercise such registration rights for a period of not less than 180 days after the date of this prospectus. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the United States Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder's particular circumstances, including the impact of the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to non-U.S. holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations, partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons deemed to sell our common stock under the constructive sale provisions of the Code; and
- tax-qualified retirement plans.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND**

**DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

**Definition of a Non-U.S. Holder**

For purposes of this discussion, a "non-U.S. holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor a partnership for United States federal income tax purposes. A U.S. person is any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a United States person.

**Distributions**

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock.

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being paid in connection with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Subject to the discussions below on backup withholding and foreign accounts, if dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

#### **Sale or Other Taxable Disposition**

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or a USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) of a portion of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if such class of stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually or constructively, 5% or less of such class of our stock throughout the shorter of the five-year period ending on the date of the sale or other disposition or the non-U.S. holder's holding period for such stock.



Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to payments of dividends on our common stock we make to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns will be filed with the IRS in connection with any dividends on our common stock paid to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale of our common stock within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale of our common stock outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN, W-8BEN-E or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders.

The withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of stock on or after January 1, 2017. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we may treat the entire distribution as a dividend. Prospective investors should consult their tax advisors regarding these withholding provisions.

**UNDERWRITING (CONFLICT OF INTEREST)**

We and the underwriters named below will enter into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter will severally agree to purchase the number of shares indicated in the following table. Goldman, Sachs & Co. and Morgan Stanley & Co. LLC are acting as representatives of the underwriters.

<b>Underwriters</b>	<b>Number of Shares</b>
Goldman, Sachs & Co.	
Morgan Stanley & Co. LLC	
Leerink Partners LLC	
Janney Montgomery Scott LLC	
<b>Total</b>	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

If the underwriters sell more shares than the total number set forth in the table above, the underwriters have an option to purchase up to an additional \_\_\_\_\_ shares from us. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase \_\_\_\_\_ additional shares.

<b>Per Share</b>	<b>No Exercise</b>	<b>Full Exercise</b>
Total	\$ _____	\$ _____

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ \_\_\_\_\_ per share from the initial public offering price. If all the shares are not sold at the initial public offering price, the representative may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representative. See "Shares Eligible for Future Sale — Lock-Up Agreements".

Goldman, Sachs & Co. has agreed that for a period of 180 days immediately following the date of this prospectus, 4,331,858 shares of our Series E preferred stock, together with any shares of our common stock issuable upon conversion of such shares, shall be subject to the lock-up restrictions set forth in FINRA Rule 5110(g)(1) (which provides that in any public equity offering, any securities of the issuer acquired by an underwriter or related person during the 180 days prior to the required filing date of such offering shall not be sold during the offering or sold, transferred,

assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the public offering, except as provided in FINRA Rule 5110(g)(2)).

Prior to this offering, there has been no public market for the shares. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list the common stock on The NASDAQ Global Market under the symbol "TTOO".

In connection with this offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option granted to them. "Naked" short sales are any sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and, together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued at any time. These transactions may be effected on The NASDAQ Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail. In addition, certain of the underwriters or

securities dealers may facilitate Internet distribution for this offering to certain of its Internet subscription customers. Certain of the underwriters may allocate a limited number of shares for sale to online brokerage customers. An electronic prospectus is available on the Internet websites maintained by certain of the underwriters. Other than the prospectus in electronic format, the information on the underwriters' websites are not part of this prospectus.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We estimate that the total expenses of this offering payable by us, excluding the underwriting discount, will be approximately \$ . We have agreed to reimburse the underwriters for certain expenses in an amount up to \$ .

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

#### **Conflict of Interest**

Certain affiliates of Goldman, Sachs & Co., an underwriter of this offering, beneficially own % of our common stock as of March 31, 2014, and are together entitled to designate one member of our board of directors prior to the closing of this offering. As a result, Goldman, Sachs & Co. is deemed to have a "conflict of interest" within the meaning of Rule 5121 of the Financial Industry Regulatory Authority, or FINRA. Accordingly, this offering will be made in compliance with the applicable provisions of FINRA Rule 5121. FINRA Rule 5121 prohibits Goldman, Sachs & Co. from making sales to discretionary accounts without the prior written approval of the account holder and requires that a "qualified independent underwriter," as defined in FINRA Rule 5121, participate in the preparation of the registration statement, of which this prospectus forms a part, and exercise its usual standards of due diligence with respect thereto. Morgan Stanley & Co. LLC has agreed to act as "qualified independent underwriter" for this offering. Morgan Stanley & Co. LLC will not receive any additional fees for serving as "qualified independent underwriter" in connection with this offering. We have agreed to indemnify Morgan Stanley & Co. LLC against certain liabilities incurred in connection with acting as "qualified independent underwriter," including liabilities under the Securities Act and to contribute to payments that Morgan Stanley & Co. LLC may be required to make in that respect.

#### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory, commercial banking and investment banking services for the issuer or its affiliates, for which they received or will receive customary fees and expenses. Certain affiliates of Goldman, Sachs & Co. own interests in our company as described in " — Conflict of Interest" above.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities or instruments of the issuer. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

## European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

- (1) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (2) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant underwriter or underwriters nominated by the Issuer for any such offer; or
- (3) in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3(2) of the Prospectus Directive;

provided that no such offer of shares shall require the Issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

## United Kingdom

Each underwriter has represented and agreed that:

- (1) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the Issuer; and
- (2) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

## Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies

Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

## **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

## **Japan**

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Cooley LLP, New York, New York.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2012 and 2013, and for the years then ended and for the period from April 27, 2006 (inception) to December 31, 2013, as set forth in their report. We have included our financial statements in the prospectus in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the Public Reference Room of the Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is [www.sec.gov](http://www.sec.gov).

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of  
T2 Biosystems, Inc.

We have audited the accompanying balance sheets of T2 Biosystems, Inc. (a development stage enterprise) (the Company) as of December 31, 2012 and 2013, and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' (deficit) equity and cash flows for the years then ended and the period from April 27, 2006 (inception) to December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of T2 Biosystems, Inc. (a development stage enterprise) as of December 31, 2012 and 2013 and the results of its operations and its cash flows for the years then ended and the period from April 27, 2006 (inception) to December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts  
April 24, 2014

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Balance Sheets**

(In thousands, except share and per share data)

	December 31, 2012	December 31, 2013	March 31, 2014 Actual (unaudited)	March 31, 2014 Pro forma (unaudited)
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 9,709	\$ 30,198	\$ 23,698	\$
Prepaid expenses and other current assets	60	195	247	
Restricted cash, current portion	80	—	—	
Total current assets	9,849	30,393	23,945	
Property and equipment, net	1,195	1,118	1,237	
Restricted cash, net of current portion	340	340	340	
Other assets	47	34	310	
Total assets	<u>\$ 11,431</u>	<u>\$ 31,885</u>	<u>\$ 25,832</u>	<u>\$</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity</b>				
Current liabilities:				
Accounts payable	\$ 571	\$ 943	\$ 1,035	\$
Accrued expenses	733	1,319	2,372	
Current portion of notes payable	820	1,759	1,764	
Current portion of deferred rent	5	25	30	
Total current liabilities	2,129	4,046	5,201	
Notes payable, net of current portion	5,058	3,299	2,855	
Deferred rent, net of current portion	70	45	35	
Warrants to purchase redeemable securities	695	1,225	1,152	
Commitments and contingencies (Note 14)				
Redeemable convertible preferred stock (Note 7)	66,137	112,813	114,719	
Stockholders' (deficit) equity:				
Common stock, \$0.001 par value; 19,926,408, 28,254,907 and 28,254,907 shares authorized at December 31, 2012 and 2013 and March 31, 2014 (unaudited), respectively; 2,315,512, 2,400,422 and 2,400,422 shares issued and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited), respectively; shares issued and outstanding pro forma (unaudited)	2	2	2	
Additional paid-in capital	—	—	—	
Deficit accumulated during the development stage	(62,660)	(89,545)	(98,132)	
Total stockholders' (deficit) equity	<u>(62,658)</u>	<u>(89,543)</u>	<u>(98,130)</u>	
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	<u>\$ 11,431</u>	<u>\$ 31,885</u>	<u>\$ 25,832</u>	<u>\$</u>

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Statements of Operations and Comprehensive Loss**

(In thousands, except share and per share data)

	Year Ended		Three Months Ended		Period from
	December 31,		March 31,		April 27,
	2012	2013	2013	2014	2006
			(unaudited)	(unaudited)	(Inception) to
					March 31,
					2014
					(unaudited)
Research and grant revenue	\$ 19	\$ 266	\$ —	\$ —	\$ 3,085
Operating expenses:					
Research and development	11,727	14,936	3,561	5,065	59,388
Selling, general and administrative	2,945	5,022	1,039	1,842	22,552
Total operating expenses	14,672	19,958	4,600	6,907	81,940
Loss from operations	(14,653)	(19,692)	(4,600)	(6,907)	(78,855)
Interest expense, net	(154)	(403)	(105)	(86)	(937)
Other income (expense), net	352	(515)	125	73	611
Net loss	<u>\$ (14,455)</u>	<u>\$ (20,610)</u>	<u>\$ (4,580)</u>	<u>\$ (6,920)</u>	<u>\$ (79,181)</u>
Comprehensive loss	<u>\$ (14,455)</u>	<u>\$ (20,610)</u>	<u>\$ (4,580)</u>	<u>\$ (6,920)</u>	<u>\$ (79,181)</u>
Reconciliation of net loss to net loss applicable to common stockholders:					
Net loss	\$ (14,455)	\$ (20,610)	\$ (4,580)	\$ (6,920)	\$ (79,181)
Accretion of redeemable convertible preferred stock to redemption value	\$ (4,412)	\$ (6,908)	\$ (1,176)	\$ (1,906)	\$ (21,307)
Net loss applicable to common stockholders	<u>\$ (18,867)</u>	<u>\$ (27,518)</u>	<u>\$ (5,756)</u>	<u>\$ (8,826)</u>	<u>\$ (100,488)</u>
Net loss per share applicable to common stockholders – basic and diluted	<u>\$ (8.15)</u>	<u>\$ (11.60)</u>	<u>\$ (2.45)</u>	<u>\$ (3.68)</u>	<u>\$ (58.62)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders – basic and diluted	<u>2,314,832</u>	<u>2,372,542</u>	<u>2,346,601</u>	<u>2,400,422</u>	<u>1,714,171</u>
Pro forma net loss per share applicable to common stockholders — basic and diluted (unaudited)		<u>\$</u>		<u>\$</u>	<u>\$</u>
Pro forma weighted-average number of common shares used in computing pro forma net loss per share applicable to common stockholders — basic and diluted (unaudited)		<u></u>		<u></u>	<u></u>

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity**  
**(In thousands, except share and per share data)**

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' (Deficit) Equity	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of April 27, 2006	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	18,180	—	—	—	
Issuance of Series A-1 redeemable convertible preferred stock, net of issuance costs of \$0	282,849	533	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	
Issuance of Series A-2 redeemable convertible preferred stock, net of issuance costs of \$0	—	—	1,703,959	4,845	—	—	—	—	—	—	—	—	—	—	—	—	—	
Accretion of Series A-1 and A-2 redeemable convertible preferred stock to redemption value	—	20	—	21	—	—	—	—	—	—	—	—	—	—	(31)	(10)	(41)	
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	590,610	1	5	—	6
Issuance of common stock for services	—	—	—	—	—	—	—	—	—	—	—	—	—	49,903	—	9	—	9
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	17	—	—	17
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(496)	—	(496)
Balance at December 31, 2006	282,849	553	1,703,959	4,866	—	—	—	—	—	—	—	—	—	658,693	1	—	(506)	(505)
Accretion of Series A-1 and A-2 redeemable convertible preferred stock to redemption value	—	48	—	418	—	—	—	—	—	—	—	—	—	—	(80)	(386)	(466)	
Issuance of common stock for services	—	—	—	—	—	—	—	—	—	—	—	—	—	34,775	—	7	—	7
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	337,464	—	3	—	3
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	70	—	—	70
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(2,842)	—	(2,842)
Balance at December 31, 2007	282,849	601	1,703,959	5,284	—	—	—	—	—	—	—	—	—	1,030,932	1	—	(3,734)	(3,733)

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity (Continued)**  
**(In thousands, except share and per share data)**

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$0	—	\$ —	—	\$ —	3,249,877	\$ 10,722	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—
Accretion of Series A-1, A-2, and B redeemable convertible preferred stock to redemption value	—	46	—	411	—	369	—	—	—	—	—	—	—	—	(133)	(693)	(826)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	28,623	—	8	—	8
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	415,750	—	25	—	25
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	100	—	100
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,964)	(5,964)
Balance at December 31, 2008	282,849	647	1,703,959	5,695	3,249,877	11,091	—	—	—	—	—	—	1,475,305	1	—	(10,391)	(10,390)
Accretion of Series A-1, A-2, and B redeemable convertible preferred stock to redemption value	—	46	—	411	—	880	—	—	—	—	—	—	—	—	(243)	(1,094)	(1,337)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	11,770	—	3	—	3
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	409,728	1	23	—	24
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	217	—	217
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,390)	(5,390)
Balance at December 31, 2009	282,849	693	1,703,959	6,106	3,249,877	11,971	—	—	—	—	—	—	1,896,803	2	—	(16,875)	(16,873)

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity (Continued)**  
**(In thousands, except share and per share data)**

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of \$154	—	\$ —	—	\$ —	—	\$ —	4,055,125	\$14,691	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—
Accretion of Series A-1, A-2, B, and C redeemable convertible preferred stock to redemption value	—	46	—	408	—	876	—	775	—	—	—	—	—	—	(284)	(1,821)	(2,105)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	16,493	—	7	—	7
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	269,262	—	22	—	22
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	255	—	255
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(7,234)	(7,234)
Balance at December 31, 2010	282,849	739	1,703,959	6,514	3,249,877	12,847	4,055,125	15,466	—	—	—	—	2,182,558	2	—	(25,930)	(25,928)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of \$147	—	—	—	—	—	—	—	—	5,054,945	22,853	—	—	—	—	—	—	—
Accretion of Series A-1, A-2, B, C, and D redeemable convertible preferred stock to redemption value	—	45	—	404	—	873	—	1,215	—	769	—	—	—	—	(309)	(2,997)	(3,306)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	62,718	—	19	—	19
Vesting of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	66,284	—	18	—	18
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	272	—	272
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(15,270)	(15,270)
Balance at December 31, 2011	282,849	784	1,703,959	6,918	3,249,877	13,720	4,055,125	16,681	5,054,945	23,622	—	—	2,311,560	2	—	(44,197)	(44,195)

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity (Continued)**  
**(In thousands, except share and per share data)**

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Accretion of Series A-1, A-2, B, C, and D redeemable convertible preferred stock to redemption value	—	\$ 46	—	\$ 404	—	\$ 874	—	\$ 1,214	—	\$ 1,874	—	\$ —	—	\$ —	(404)	\$ (4,008)	\$ (4,412)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	3,952	—	1	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	403	—	4
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(14,455)	(14,455)
Balance at December 31, 2012	282,849	830	1,703,959	7,322	3,249,877	14,594	4,055,125	17,895	5,054,945	25,496	—	—	2,315,512	2	—	(62,660)	(62,660)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of \$232	—	—	—	—	—	—	—	—	—	—	6,930,967	39,768	—	—	—	—	—
Accretion of Series A-1, A-2, B, C, D, and E redeemable convertible preferred stock to redemption value	—	44	—	402	—	870	—	1,205	—	1,861	—	2,526	—	—	(633)	(6,275)	(6,908)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	84,910	—	55	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	578	—	5
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(20,610)	(20,610)
Balance at December 31, 2013	282,849	\$ 874	1,703,959	\$ 7,724	3,249,877	\$ 15,464	4,055,125	\$ 19,100	5,054,945	\$ 27,357	6,930,967	\$ 42,294	2,400,422	\$ 2	\$ —	\$ (89,545)	\$ (89,545)

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity (Continued)**  
**(In thousands, except share and per share data)**

	Series A-1 Redeemable Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Accretion of Series A-1, A-2, B, C, D, and E redeemable convertible preferred stock to redemption value	—	\$ 11	—	\$ 100	—	\$ 217	—	\$ 301	—	\$ 465	—	\$ 812	—	—	\$ (239)	\$ (1,667)	\$ (1,906)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	239	—	(6,920)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(6,920)
Balance at March 31, 2014 (unaudited)	282,849	\$ 885	1,703,959	\$ 7,824	3,249,877	\$ 15,681	4,055,125	\$ 19,401	5,054,945	\$ 27,822	6,930,967	\$ 43,106	2,400,422	\$ 2	—	\$ (98,132)	\$ (98,132)
Conversion of convertible preferred stock into common stock (unaudited)		\$		\$		\$		\$		\$		\$		\$		\$	\$
Issuance of common stock upon net exercise of and reclassification of warrants to purchase redeemable convertible preferred stock (unaudited)																	
Pro forma balance at March 31, 2014 (unaudited)		\$		\$		\$		\$		\$		\$		\$		\$	\$

See accompanying notes to financial statements.



**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Statements of Cash Flows**

(In thousands)

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013 (unaudited)	2014 (unaudited)	2014 (unaudited)
<b>Operating activities</b>					
Net loss	\$ (14,455)	\$ (20,610)	\$ (4,580)	\$ (6,920)	\$ (79,181)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	571	584	138	144	3,180
Stock-based compensation expense	403	578	122	239	2,150
Noncash interest expense	46	44	11	11	245
Noncash warrant expense	81	—	—	—	598
Change in fair value of warrants	(132)	530	(110)	(73)	346
Loss on disposal of asset	—	6	—	—	6
Stock-based license fees	—	—	—	—	16
Deferred rent	15	(5)	—	(6)	64
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	(2)	(138)	(108)	(52)	(233)
Accounts payable	(88)	372	38	93	1,036
Accrued expenses	258	586	622	773	2,092
Net cash used in operating activities	<u>(13,303)</u>	<u>(18,053)</u>	<u>(3,867)</u>	<u>(5,791)</u>	<u>(69,681)</u>
<b>Investing activities</b>					
Purchases of property and equipment	(283)	(513)	(115)	(263)	(4,423)
Decrease (increase) in restricted cash	—	80	80	—	(340)
Net cash used in investing activities	<u>(283)</u>	<u>(433)</u>	<u>(35)</u>	<u>(263)</u>	<u>(4,763)</u>
<b>Financing activities</b>					
Proceeds from issuance of redeemable convertible preferred stock, net	—	39,768	39,768	—	93,412
Proceeds from issuance of common stock and stock options exercises, net	1	55	33	—	93
Proceeds from issuance of restricted stock	—	—	—	—	99
Proceeds from issuance of note payable, net	4,924	—	—	—	8,331
Repayments of note payable	(374)	(848)	(52)	(446)	(3,793)
Net cash provided by (used in) financing activities	<u>4,551</u>	<u>38,975</u>	<u>39,749</u>	<u>(446)</u>	<u>98,142</u>
Net (decrease) increase in cash and cash equivalents	(9,035)	20,489	35,847	(6,500)	23,698
Cash and cash equivalents at beginning of period	18,744	9,709	9,709	30,198	—
Cash and cash equivalents at end of period	<u>\$ 9,709</u>	<u>\$ 30,198</u>	<u>\$ 45,556</u>	<u>\$ 23,698</u>	<u>\$ 23,698</u>

See accompanying notes to financial statements.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**  
**Statements of Cash Flows (Continued)**  
**(In thousands)**

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013	2014	(unaudited)
<b>Supplemental disclosures of cash flow information</b>					
Cash paid for interest	\$ 101	\$ 345	\$ 62	\$ 51	\$ 910
<b>Supplemental disclosures of noncash investing and financing activities</b>					
Accretion of Series A-1, A-2, B, C, D and E redeemable convertible preferred stock to redemption value	\$ 4,412	\$ 6,908	\$ 1,176	\$ 1,906	\$ 21,307
Warrants issued in connection with debt	\$ 64	\$ —	\$ —	\$ —	\$ 280
Warrants issued in connection with development agreement	\$ —	\$ —	\$ —	\$ —	\$ 598
Initial public offering costs incurred but unpaid at period end	\$ —	\$ —	\$ —	\$ 280	\$ 280

See accompanying notes to financial statements.

**T2 Biosystems, Inc.  
(A Development Stage Company)**

**Notes to Financial Statements**

**Years Ended December 31, 2012 and 2013, Three Months  
Ended March 31, 2013 and 2014 and the Period from  
April 27, 2006 (Inception) to March 31, 2014**

**1. Nature of Business**

T2 Biosystems, Inc. (the "Company") was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an *in vitro* diagnostic company that has developed an innovative and proprietary platform that enables rapid, sensitive and simple direct detection of pathogens, biomarkers and other abnormalities across a variety of unpurified patient sample types. The Company is using its T2 Magnetic Resonance platform ("T2MR") to develop a broad set of applications aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. The Company's initial development efforts target sepsis and hemostasis, areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. The Company has completed a pivotal clinical trial for T2Dx and T2Candida.

Since inception, the Company has devoted substantially all of its efforts to research and development, business planning, recruiting management and technical staff, acquiring operating assets and raising capital. The Company has not recognized any revenue from its planned principal operations, and as a result, is considered to be in the development stage.

**Liquidity**

At December 31, 2013 and March 31, 2014, the Company has a deficit accumulated in the development stage of \$89,545,000 and \$98,132,000, respectively. The future success of the Company is dependent on its ability to obtain additional capital to develop its product candidates and ultimately upon its ability to attain profitable operations. To date, the Company has funded its operations primarily through private placements of its redeemable convertible preferred stock and through debt financing arrangements. Management believes that its cash resources of \$30,198,000 at December 31, 2013 will be sufficient to allow the Company to fund its current operating plan and continue as a going concern through at least January 1, 2015. Thereafter, the Company will be required to obtain additional funding, alternative means of financial support, or both, in order to continue to fund its operations. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company is subject to a number of risks similar to other life science companies in the development stage, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, development and market acceptance of the Company's product candidates, and protection of proprietary technology.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The Company's financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

**Use of Estimates**

The preparation of the Company's financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company utilizes certain estimates in the determination of the fair value of its common stock and stock options, the fair value of liability-classified warrants, deferred tax valuation allowances, revenue recognition, and to record expenses relating to research and development contracts. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from such estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

**Unaudited Interim Financial Information**

The accompanying interim balance sheet as of March 31, 2014, the statements of operations and comprehensive loss and statements of cash flows for the three months ended March 31, 2013 and 2014 and for the period from April 27, 2006 (inception) to March 31, 2014, the statement of redeemable convertible preferred stock and stockholders' equity (deficit) for the three months ended March 31, 2014, and the financial data and other information disclosed in these notes related to the three months ended March 31, 2013 and 2014 and for the period from April 27, 2006 (inception) to March 31, 2014 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2014, and the results of its operations and its cash flows for the three months ended March 31, 2013 and 2014 and for the period from April 27, 2006 (inception) to March 31, 2014. The results for the three months ended

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

March 31, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period.

**Unaudited Pro Forma Presentation**

In 2014, the Company's board of directors authorized the management of the Company to file a registration statement with the U.S. Securities and Exchange Commission ("SEC") for the Company to sell shares of its common stock to the public. Upon the closing of a qualified (as defined in the Company's Articles of Incorporation) initial public offering ("IPO") or otherwise upon the election of the holders of the specified percentage of redeemable convertible preferred stock, all outstanding shares of redeemable convertible preferred stock will automatically convert into common stock. The unaudited pro forma balance sheet and statement of redeemable convertible preferred stock and stockholders' (deficit) equity as of March 31, 2014 assumes the automatic conversion of all outstanding redeemable convertible preferred stock into shares of common stock and reflects the issuance of shares of common stock associated with the expected net exercise of outstanding warrants exercisable for redeemable convertible preferred stock, including the resulting reclassification of the related liability for warrants to purchase redeemable securities to additional paid-in capital, upon the completion of the proposed offering. Additionally, the unaudited pro forma balance sheet and statement of redeemable convertible preferred stock and stockholders' (deficit) equity as of March 31, 2014 reflects the assumed allocation of value to occur upon the automatic conversion of all outstanding redeemable convertible preferred stock into shares of common stock whereupon deficit accumulated during the development stage has been restored for the cumulative accretion to redemption value of redeemable convertible preferred stock recorded through March 31, 2014, while the remainder of value is reflected within common stock and additional paid-in capital.

Unaudited pro forma basic and diluted net loss per share was calculated by dividing net loss applicable to common stockholders, excluding accretion to redemption value of redeemable convertible preferred stock and changes in the fair value of the liability for warrants to purchase redeemable securities, by the pro forma weighted-average number of common shares outstanding. The unaudited pro forma weighted-average number of common shares outstanding was computed after giving effect to the assumed conversion of the redeemable convertible preferred stock into shares of common stock and the expected issuance of common stock upon the cashless exercise of warrants to purchase redeemable convertible preferred stock, as if such conversion and net exercise had occurred at the beginning of the period presented, or the date of original issuance, if later. Upon conversion of the redeemable convertible preferred stock into shares of the Company's common stock in the event of an initial public offering, the holders of the redeemable convertible preferred stock are not entitled to receive undeclared dividends.

**Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

Company's chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and, upon regulatory clearance, launching commercially its diagnostic products aimed at reducing mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

**Off-Balance Sheet Risk and Concentrations of Credit Risk**

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. At December 31, 2012 and 2013, and March 31, 2014, substantially all of the Company's cash was deposited in accounts at one financial institution, with a significant amount invested in money market funds that are invested in short-term U.S. Treasury bills. The Company maintains its cash and cash equivalents, which at times may exceed the federally insured limits, with a large financial institution and, accordingly, the Company believes such funds are subject to minimal credit risk.

**Cash Equivalents**

Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. Cash equivalents consist of money market funds invested in short-term U.S. Treasury bills as of December 31, 2012 and 2013, and March 31, 2014.

**Revenue Recognition**

The Company generates revenue primarily from research and development agreements with government agencies and other third parties. Revenues earned from activities performed pursuant to development agreements is reported as revenue in the statements of operations and comprehensive loss, using the proportional performance method as the work is completed, and the related costs are expensed as incurred as research and development expense.

The timing of cash received from the Company's research and development agreements generally differs from when revenue is recognized. The Company recognizes revenue in accordance with FASB ASC Topic 605, *Revenue Recognition* ("ASC 605"). Accordingly, the Company recognizes revenue when all of the following criteria have been met:

- i. Persuasive evidence of an arrangement exists
- ii. Delivery has occurred or services have been rendered
- iii. The seller's price to the buyer is fixed or determinable
- iv. Collectability is reasonably assured

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Criterion (i) is satisfied when the Company has a written agreement or contract in place. Criterion (ii) is satisfied when the Company performs the services. Determination of criteria (iii) and

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

(iv) are based on management's judgments regarding whether the fee is fixed or determinable and the collectability of the fee is reasonably assured.

Revenue from fixed-fee government grants is recognized as the activities are performed in accordance with the terms of the grant.

The Company evaluates consideration given to its customers in accordance with ASC Topic 605-50, *Customer Payments and Incentives* ("ASC 605-50"). Consideration given to a customer is recorded as an expense in the statement of operations in those limited cases when the Company both receives an identifiable benefit in exchange for the consideration and the Company can reasonably estimate the fair value of the identified benefit. Otherwise, the consideration is recorded as a reduction of revenue.

**Fair Value Measurements**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 — Quoted unadjusted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all observable inputs and significant value drivers are observable in active markets.

Level 3 — Model derived valuations in which one or more significant inputs or significant value drivers are unobservable, including assumptions developed by the Company.

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability (See Note 3).

Financial instruments measured at fair value on a recurring basis include cash, money market funds, restricted cash (See Note 3) and warrants to purchase redeemable securities (See Note 10).

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

For certain financial instruments, including accounts payable and accrued expenses, the carrying amounts approximate their fair values as of December 31, 2012 and 2013 and March 31, 2014 because of their short-term nature. At December 31, 2013 and March 31, 2014, the carrying value of the Company's debt approximated fair value, which was determined using Level 3 inputs, including a quoted rate.

**Property and Equipment**

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

**Research and Development Costs**

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities and include salaries and benefits, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

**Deferred IPO Issuance Costs**

Deferred IPO issuance costs, which primarily consist of direct and incremental legal and accounting fees relating to the IPO, are capitalized. The deferred IPO issuance costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, or delayed more than 90 days, deferred offering costs will be expensed. No amounts were deferred as of December 31, 2012 and 2013. As of March 31, 2014, \$0.3 million of deferred IPO issuance costs were recorded in other assets and accrued expenses in the accompanying balance sheet.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. During this review, the Company reevaluates the significant assumptions used in determining the original cost and estimated lives of long-lived assets. Although the assumptions may vary from asset to asset, they generally include operating results, changes in the use of the asset, cash flows and other indicators of value. Management then determines whether the remaining useful life continues to be appropriate or whether there has been an impairment of long-lived assets based primarily upon whether expected future undiscounted cash flows are sufficient to support the assets' recovery. If impairment exists, the Company would adjust the carrying value of the asset to fair value, generally determined by a discounted cash flow analysis. No impairment charges have been recorded in any of the periods presented.



**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss consists of net loss and other comprehensive loss, which includes certain changes in equity that are excluded from net loss. The Company's comprehensive loss equals reported net loss for all periods presented.

**Stock-Based Compensation**

The Company has a stock-based compensation plan which is more fully described in Note 9. The Company records stock-based compensation for options granted to employees and to members of the board of directors for their services on the board of directors, based on the grant date fair value of awards issued, and the expense is recorded on a straight-line basis over the applicable service period, which is generally four years. The Company accounts for non-employee stock-based compensation arrangements based upon the fair value of the consideration received or the equity instruments issued, whichever is more reliably measurable. The measurement date for non-employee awards is generally the date that the performance of services required for the non-employee award is complete. Stock-based compensation costs for non-employee awards is recognized as services are provided, which is generally the vesting period, on a straight-line basis.

The Company expenses restricted stock awards based on the fair value of the award on a straight-line basis over the associated service period of the award.

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The use of the Black-Scholes-Merton option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The expected term was determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics were selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computed the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock-based awards. The risk-free interest rate is determined by reference to U.S. Treasury zero-coupon issues with remaining maturities similar to the expected term of the options. The Company has not paid, and does not anticipate paying, cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero. The Company is required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Warrants to Purchase Redeemable Securities**

The Company has issued warrants to purchase shares of the Company's series A-2 redeemable convertible preferred stock, series B redeemable convertible preferred stock, series C redeemable convertible preferred stock, and series D redeemable convertible preferred stock.

The Company accounts for warrant instruments that either conditionally or unconditionally obligate the issuer to transfer assets as liabilities regardless of the timing of the redemption feature or price, even though the underlying shares may be classified as permanent or temporary equity. Consequently, the warrants to purchase shares of series A-2 preferred stock, series B preferred stock, series C preferred stock, and series D preferred stock are accounted for as liabilities and adjusted to fair value at the end of each reporting period. The liability for warrants to purchase redeemable securities is remeasured at each balance sheet date with changes to fair value being recognized as a component of other income (expense) in the statement of operations and comprehensive loss. The Company will continue to remeasure the fair value of the liability for warrants to purchase redeemable securities at the end of each reporting period until the earlier of the exercise or expiration of the applicable warrants or until such time that the underlying redeemable convertible preferred stock is converted into common stock and reclassified to permanent equity.

**Income Taxes**

The Company provides for income taxes using the liability method. The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

The Company applies ASC 740 *Income Taxes* ("ASC 740") in accounting for uncertainty in income taxes. The Company does not have any material uncertain tax positions for which reserves would be required. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

**Guarantees**

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that limits its exposure and enables it to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands,

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's leases.

As of December 31, 2013 and March 31, 2014, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

**Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, warrants to purchase redeemable convertible preferred stock, stock options and unvested restricted stock are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect, including the related impact to the numerator of the fair value adjustment of the warrant and the impact to the denominator of the warrant shares, would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

**Recently Adopted Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

**3. Fair Value Measurements**

The Company measures the following financial assets and liabilities at fair value on a recurring basis. Except for the valuation methodology used to measure the liability for warrants to purchase redeemable securities (see Note 10), during the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. There were no transfers between levels of the fair value hierarchy during any of the periods presented. The following tables set forth the Company's financial assets and liabilities carried at fair

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**3. Fair Value Measurements (Continued)**

value categorized using the lowest level of input applicable to each financial instrument as of December 31, 2012 and 2013 and March 31, 2014 (in thousands):

	Balance at December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash	\$ 398	\$ 398	\$ —	\$ —
Money market funds	9,311	9,311	—	—
Restricted cash	420	420	—	—
	<u>\$ 10,129</u>	<u>\$ 10,129</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrants to purchase redeemable securities	\$ 695	\$ —	\$ —	\$ 695
	<u>\$ 695</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 695</u>
	Balance at December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash	\$ 2,631	\$ 2,631	\$ —	\$ —
Money market funds	27,567	27,567	—	—
Restricted cash	340	340	—	—
	<u>\$ 30,538</u>	<u>\$ 30,538</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrants to purchase redeemable securities	\$ 1,225	\$ —	\$ —	\$ 1,225
	<u>\$ 1,225</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,225</u>

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**3. Fair Value Measurements (Continued)**

	Balance at March 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash	\$ 2,130	\$ 2,130	\$ —	\$ —
Money market funds	21,568	21,568	—	—
Restricted cash	340	340	—	—
	<u>\$ 24,038</u>	<u>\$ 24,038</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Warrants to purchase redeemable securities	\$ 1,152	\$ —	\$ —	\$ 1,152
	<u>\$ 1,152</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,152</u>

The following table sets forth a summary of changes in the fair value of the Company's preferred stock warrant liability (See Note 10), which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
	Beginning balance	\$ 763	\$ 695	\$ 695
Additional warrants issued	64	—	—	—
Change in fair value, recorded as a component of other income (expense)	(132)	530	(110)	(73)
Ending balance	<u>\$ 695</u>	<u>\$ 1,225</u>	<u>\$ 585</u>	<u>\$ 1,152</u>

**4. Restricted Cash**

The Company is required to maintain a security deposit for its operating lease agreement for the duration of the lease agreement and for its credit cards as long as they are in place. At December 31, 2012 and 2013 and March 31, 2014, the Company had certificates of deposit for \$420,000, \$340,000 and \$340,000, respectively, which represented collateral as security deposits for its operating lease agreement for its facility and its credit card. In accordance with the operating lease agreement, the Company reduced its security deposit by \$80,000 to \$320,000 on January 14, 2013.

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**5. Supplemental Balance Sheet Information**

**Property and Equipment**

Property and equipment consists of the following (in thousands):

	<u>Estimated Useful Life (Years)</u>	<u>December 31,</u>		<u>March 31,</u>
		<u>2012</u>	<u>2013</u>	<u>2014</u>
Office and computer equipment	3	\$ 300	\$ 302	\$ 303
Software	3	186	186	199
Laboratory equipment	5	2,440	2,770	2,879
Furniture	5 - 7	171	179	179
Leasehold improvements	Lesser of useful life or lease term	175	332	332
Construction in progress	n/a	—	—	140
		<u>3,272</u>	<u>3,769</u>	<u>4,032</u>
Less accumulated depreciation and amortization		<u>(2,077)</u>	<u>(2,651)</u>	<u>(2,795)</u>
Property and equipment, net		<u>\$ 1,195</u>	<u>\$ 1,118</u>	<u>\$ 1,237</u>

Construction in progress is primarily comprised of capitalized internal use software costs related to projects that have not been placed in service.

Depreciation and amortization expense of \$571,000, \$584,000, \$138,000, \$144,000 and \$3,180,000 was charged to operations for the years ended December 31, 2012 and 2013, the three months ended March 31, 2013 and 2014 and for the period from April 27, 2006 (inception) to March 31, 2014, respectively.

**Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	<u>December 31,</u>		<u>March 31,</u>
	<u>2012</u>	<u>2013</u>	<u>2014</u>
Accrued payroll and compensation	\$ 384	\$ 496	\$ 388
Accrued professional services	120	101	517
Accrued research and development expenses	101	422	916
Other accrued expenses	128	300	551
Total accrued expenses	<u>\$ 733</u>	<u>\$ 1,319</u>	<u>\$ 2,372</u>

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**6. Debt**

**Secured Notes Payable**

On August 30, 2007, the Company entered into a loan and security agreement ("Note Agreement 1") with a lender to borrow up to \$2,000,000 for the purchase of laboratory equipment and office equipment through August 30, 2008. On June 26, 2009, the Company entered into a loan modification agreement with the lender which provided additional borrowing of up to \$1,500,000 through June 25, 2010.

The amounts borrowed are collateralized by the assets of the Company, bear interest between 5.5% and 10.3%, and are payable in 36 or 48 monthly installments. Note Agreement 1 requires a final payment of 1.6% to 3.75% of the aggregate original principal amount of each borrowing. This final payment is recorded as deferred financing cost and amortized to interest expense over the term of the borrowing. No amounts remain outstanding under Note Agreement 1 as of December 31, 2013.

On May 9, 2011, the Company entered into a promissory agreement ("Note Agreement 2") with a separate lender to borrow up to \$1,688,000 for the purchase of laboratory equipment and office equipment through December 2013. The amounts borrowed are collateralized by the associated equipment and bear interest at 6.5%. The Company paid interest only on the borrowings through December 2013 and will make equal monthly payments of principal and interest through the maturity date of May 2018. During 2012 the Company borrowed \$451,000 under the agreement.

The Note Agreement 2 includes financial covenants that require the Company to maintain a minimum cash balance of \$300,000.

On June 25, 2012, the Company entered into a loan and security agreement ("Note Agreement 3") with the same lender as Note Agreement 1 to borrow up to \$4,500,000 for operations through December 31, 2012. The amounts borrowed are collateralized by the assets of the Company and bear interest at 6.25%. The Company paid interest only on the borrowings through June 30, 2013 and then makes 36 equal month payments of principal plus monthly payments of accrued interest. During 2012, the Company borrowed \$4,500,000 under the agreement. The debt can be prepaid at the option of the Company, and is subject to a prepayment premium of 2% if it is repaid prior the first anniversary of the borrowing date, and 1% if the debt is prepaid prior to the second anniversary of the borrowing date.

In addition, Note Agreement 2 contains a subjective acceleration clause whereby an event of default and immediate acceleration of the borrowing under the security and loan agreement occurs if there is a material adverse change in the business, operations, or condition (financial or otherwise) of the Company or a material impairment of the prospect of repayment of any portion of the obligations. The lender has not exercised its right under this clause, as there have been no such events. The Company believes that the likelihood of the lender exercising this right is remote.

Interest expense for the years ended December 31, 2012 and 2013, was \$156,000 and \$410,000, respectively, and for the three months ended March 31, 2013 and 2014 was \$106,000 and \$87,000, respectively, and was \$1,181,000 for the cumulative period from April 27, 2006 (inception) to March 31, 2014.

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**6. Debt (Continued)**

During 2007, the Company issued a fully vested warrant to purchase 13,769 shares of the Company's series A-2 preferred stock in connection with Note Agreement 1. In 2009, the Company issued a fully vested warrant to purchase 9,036 shares of the Company's series B preferred stock in connection with the modification of Note Agreement 1. In 2011, the Company issued a fully vested warrant to purchase 30,000 shares of the Company's series C preferred stock in connection with Note Agreement 2. In 2012, the Company issued a fully vested warrant to purchase 19,780 shares of the Company's series D preferred stock in connection with Note Agreement 3. The fair market value of the warrants at issuance, in the aggregate amount of \$208,000, was recorded as a debt discount and is being amortized as additional interest expense over the term of the notes. The Company recognized \$25,000, \$29,000, \$7,000, and \$7,000 of additional interest expense for the years ended December 31, 2012 and 2013 and for the three months ended March 31, 2013 and 2014, respectively, and \$121,000 for the cumulative period from April 27, 2006 (inception) to March 31, 2014, associated with the amortization of the debt discount related to the warrants issued.

Future principal payments on the notes payable as of December 31, 2013 are as follows (in thousands):

Year ended December 31,	
2014	\$ 1,788
2015	1,808
2016	1,079
2017	351
2018	126
Total debt payments	5,152
Less current portion	(1,759)
Less debt discount	(94)
Notes payable, net of current portion	<u>\$ 3,299</u>



**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**7. Redeemable Convertible Preferred Stock**

The Company's Preferred Stock consisted of the following (in thousands, except share and per share data):

	<u>December 31,</u>		<u>March 31, 2014</u>	
	<u>2012</u>	<u>2013</u>	<u>Actual</u>	<u>Pro Forma</u> <u>(unaudited)</u>
Series A-1 redeemable convertible preferred stock \$0.001 par value; 282,849 shares authorized, issued, and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$877 at December 31, 2013 and \$888 at March 31, 2014)	\$ 830	\$ 874	\$ 885	\$ —
Series A-2 redeemable convertible preferred stock \$0.001 par value; 1,717,728 shares authorized; 1,703,959 shares issued and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$7,744 at December 31, 2013 and \$7,843 at March 31, 2014)	7,322	7,724	7,824	—
Series B redeemable convertible preferred stock \$0.001 par value; 3,523,765 shares authorized; 3,249,877 shares issued and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$15,485 at December 31, 2013 and \$15,701 at March 31, 2014)	14,594	15,464	15,681	—
Series C redeemable convertible preferred stock \$0.001 par value; 4,085,125 shares authorized; 4,055,125 shares issued and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$19,166 at December 31, 2013 and \$19,463 at March 31, 2014)	17,895	19,100	19,401	—
Series D redeemable convertible preferred stock \$0.001 par value; 5,074,725 shares authorized; 5,054,945 shares issued and outstanding at December 31, 2012 and 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$27,441 at December 31, 2013 and \$27,901 at March 31, 2014)	25,496	27,375	27,822	—
Series E redeemable convertible preferred stock \$0.001 par value; no shares authorized at December 31, 2012 and 6,960,967 shares authorized at December 31, 2013 and March 31, 2014; no shares issued and outstanding at December 31, 2012 and 6,930,967 shares issued and outstanding at December 31, 2013 and March 31, 2014 (unaudited); no shares issued and outstanding pro forma (unaudited); (liquidation preference of \$42,490 at December 31, 2013 and \$43,290 at March 31, 2014)	—	42,294	43,106	—
<b>Total redeemable convertible preferred stock</b>	<u>\$ 66,137</u>	<u>\$ 112,831</u>	<u>\$ 114,719</u>	<u>\$ —</u>

As of December 31, 2013 and March 31, 2014, the authorized capital stock of the Company included 21,645,159 shares of preferred stock, \$0.001 par value, of which 282,849 shares are

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**7. Redeemable Convertible Preferred Stock (Continued)**

designated series A-1 preferred stock, 1,717,728 shares are designated series A-2 preferred stock, 3,523,765 are designated series B preferred stock, 4,085,125 shares are designated series C preferred stock, 5,074,725 shares are designated series D preferred stock and 6,960,967 shares are designated series E preferred stock (collectively, "Preferred Stock").

On March 22, 2013, the Company sold and issued 6,930,967 shares of series E preferred stock at \$5.7712 per share to investors for total consideration of \$40,000,000.

On August 3, 2011, the Company issued 5,054,945 shares of series D preferred stock at \$4.55 per share to investors for total consideration of \$23,000,000.

In May 2010, the Company issued 4,055,125 shares of series C preferred stock at \$3.6608 per share to investors for total consideration of \$14,845,000.

In July 2008, the Company issued 3,159,603 shares of series B preferred stock at \$3.3232 per share to investors for total consideration of \$10,500,000. The total consideration included the conversion of \$505,000 of convertible promissory notes ("Convertible Notes") with a face value of \$500,000. In accordance with the terms of the Convertible Notes, 151,964 shares of series B preferred stock were issued to note holders upon the conversion of the Convertible Notes. In September 2008, in connection with a development agreement (see Note 12), the Company issued an additional 90,274 shares of series B preferred stock at \$3.3232 per share for total consideration of \$300,000.

In December 2006, the Company issued 1,703,959 shares of series A-2 preferred stock at \$2.905 per share for total consideration of \$4,950,000.

In July 2006, the Company issued 282,849 shares of series A-1 preferred stock at \$1.9445 per share for total consideration of \$550,000.

The Company performs assessments of all terms and features of its redeemable convertible preferred stock in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of its Preferred Stock, including conversion, liquidation and redemption features, as well as dividend and voting rights. Based on the Company's determination that each series of its Preferred Stock is an "equity host," the Company determined that the conversion features of the Preferred Stock are clearly and closely related to the equity host, and such conversion features do not require bifurcation as a derivative liability. In addition, the embedded put options related to the liquidation and redemption features do not meet the definition of a derivative and also do not require bifurcation as a derivative liability.

The Company accounts for potential beneficial conversion features under ASC 470-20, *Debt with Conversion and other Options*. At the time of each of the issuances of Preferred Stock, the common stock into which the Preferred Stock is convertible had a fair value less than the effective conversion price of the Preferred Stock and, accordingly, there was no intrinsic value on the respective commitment dates.

The rights, preferences, and privileges of the preferred stock are as follows:

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**7. Redeemable Convertible Preferred Stock (Continued)**

**Voting**

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote, except with respect to matters on which Delaware General Corporation Law requires that a vote will be by a separate class. Each preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which each share of Preferred Stock is convertible at the time of such vote.

A majority vote of the holders of Preferred Stock is required in order to amend the certificate of incorporation and the bylaws, create or authorize additional shares of Preferred Stock, effect a sale, liquidation or merger of the Company, or effect an acquisition.

A majority vote of the holders of Preferred Stock or approval of the board of directors, including the affirmative vote of the majority of board members designated by the holders of Preferred Stock, is required in order to incur debt, create a new plan for the grant of stock options or issuance of restricted stock, increase or decrease the authorized number of board members, pay or declare any dividends (except dividends payable solely in shares of common stock) or repurchase or redeem any capital stock (except redemptions of Preferred Stock or certain repurchases of common stock).

For each series of Preferred Stock, a majority vote (or, in the case of series A and series B, a 66% vote, or, in the case of the series C, a 75% vote) of the holders of that series of Preferred Stock is required to adversely amend the rights of that series of Preferred Stock.

**Dividends**

Dividends accrue on Preferred Stock from the date of issuance at a rate of 8% per annum per share. Dividends will accrue from day to day, whether or not earned or declared, and shall be cumulative and non-compounding.

**Liquidation Preference**

In the event of any liquidation, dissolution or winding up of the affairs of the Company, the holders of the then-outstanding Preferred Stock shall receive on a pari passu basis, before any payment shall be made to the holders of common stock, the greater of (1) \$1.9445 per share for series A-1 preferred stock, \$2.905 per share for series A-2 preferred stock, \$3.3232 per share for series B preferred stock, \$3.6608 per share for series C preferred stock, \$4.55 per share for series D preferred stock, and \$5.7712 per share for series E preferred stock, plus all unpaid accrued dividends, or (2) such amount per share of preferred stock payable as if converted into common stock. If the assets or surplus funds to be distributed to the holders of the Preferred Stock are insufficient to permit the payment to such holders of their full preferential amount, the assets and surplus funds legally available for distribution shall be distributed ratably among the holders of the Preferred Stock in proportion to the full preferential amount that each holder is otherwise entitled to receive. After the payment of any preferential amount to preferred stockholders, any remaining assets of the Company shall be distributed ratably among the holders of common stock.

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**Notes to Financial Statements (Continued)**

**7. Redeemable Convertible Preferred Stock (Continued)**

**Conversion**

Each share of Preferred Stock, at the option of the holder, is convertible into a number of fully paid shares of common stock as determined by dividing \$1.9445 for series A-1 preferred stock, \$2.905 for series A-2 preferred stock, \$3.3232 for series B preferred stock, \$3.6608 for series C preferred stock, \$4.55 for series D preferred stock and \$5.7712 for series E preferred stock by the conversion price in effect at the time. The initial conversion prices of series A-1, series A-2, series B, series C, series D, and series E preferred stock are \$1.9445, \$2.905, \$3.3232, \$3.6608, \$4.55 and \$5.7712 per share, respectively, and are subject to adjustment in accordance with antidilution provisions contained in the Company's articles of incorporation. Conversion is automatic immediately upon the closing of a firm commitment underwritten public offering in which the public offering price equals or exceeds \$12.4211 per share and the gross proceeds are not less than \$40,000,000, or upon the written consent of the holders of a majority of the then-outstanding shares of Preferred Stock.

**Redemption**

Commencing on March 22, 2018, the holders of at least a majority of the outstanding shares of Preferred Stock may require the Company to redeem one-third of the Preferred Stock within 60 days of the redemption election, and on each of the first and second anniversaries thereof, at \$1.9445 per share for series A-1 preferred stock, \$2.905 per share for series A-2 preferred stock, \$3.3232 per share for series B preferred stock, \$3.6608 per share for series C preferred stock, \$4.55 per share for series D preferred stock and \$5.7712 for series E preferred stock, plus accrued but unpaid dividends. The Company is accreting the shares to the redemption values over the period from issuance to the redemption date. The accretion amounts are recorded as an increase to the carrying value of the Preferred Stock with a corresponding charge to additional paid-in capital or deficit accumulated during the development stage, which amounted to \$4,412,000 and \$6,908,000 for the years ended December 31, 2012 and 2013, respectively, \$1,176,000 and \$1,906,000 for the three months ended March 31, 2013 and 2014, respectively, and \$21,307,000 for the period from April 27, 2006 (inception) to March 31, 2014. The annual accretion related to the Preferred Stock is expected to be \$7,624,000 per year during the years ending December 31, 2014, 2015, 2016 and 2017, and \$1,692,000 for the year ending December 31, 2018.

As the preferred stock may become redeemable upon an event that is outside of the control of the Company, the Preferred Stock has been classified outside of permanent equity.

**8. Stockholders' (Deficit) Equity**

**Common Stock**

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding.

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**Notes to Financial Statements (Continued)**

**8. Stockholders' (Deficit) Equity (Continued)**

The Company has reserved the following shares of common stock as of the periods presented:

	<b>December 31,</b>		<b>March 31,</b>
	<b>2012</b>	<b>2013</b>	<b>2014</b>
Conversion of Series A-1 preferred stock	282,849	282,849	282,849
Conversion of Series A-2 preferred stock	1,703,959	1,703,959	1,703,959
Conversion of Series B preferred stock	3,249,877	3,249,877	3,249,877
Conversion of Series C preferred stock	4,055,125	4,055,125	4,055,125
Conversion of Series D preferred stock	5,054,945	5,054,945	5,054,945
Conversion of Series E preferred stock	—	6,930,967	6,930,967
Warrants to purchase redeemable convertible preferred stock	250,727	250,727	250,727
Options to purchase common stock	2,378,501	3,852,257	3,880,504
Shares available for future issuance under stock incentive plan	548,203	357,069	328,822
	<u>17,524,186</u>	<u>25,737,775</u>	<u>25,737,775</u>

**9. Stock-Based Compensation**

**Stock Incentive Plan**

The Company's 2006 Stock Option Plan (the "Plan") provides for the issuance of shares of common stock in the form of incentive stock options, non-qualified stock options, awards of stock and direct stock purchase opportunities to directors, officers, employees and consultants of the Company. Generally, stock options are granted with exercise prices equal to or greater than the fair value of the common stock as determined by the board of directors, expire no later than 10 years from the date of grant, and vest over various periods not exceeding 4 years.

The board of directors has approved increases in the number of shares that may be issued under the Plan as follows:

<b>Date</b>	<b>Additional Shares</b>	<b>Total Shares</b>
January 2008	266,100	610,334
August 2008	500,000	1,110,334
May 2010	750,000	1,860,334
April 2011	400,000	2,260,334
August 2011	1,079,024	3,339,358
March 2013	1,367,532	4,706,890

As of December 31, 2013 and March 31, 2014, 357,069 and 328,822 shares, respectively, were available for future grant under the Plan.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

**Stock Options**

During the years ended December 31, 2012 and 2013, the three months ended March 31, 2013 and 2014 and for the period from April 27, 2006 (inception) to March 31, 2014, the Company granted options with an aggregate fair value of \$702,000, \$1,991,000, \$38,000, \$432,000 and \$4,529,000, respectively, which are being amortized into compensation expense over the vesting period of the options as the services are being provided. The following is a summary of option activity under the Plan (in thousands, except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	2,378,501	\$ 1.15	7.96	\$ 505
Granted	1,821,099	1.87		
Exercised	(84,910)	0.64		71
Cancelled	(262,433)	1.34		
Outstanding at December 31, 2013	3,852,257	1.49	8.23	11,510
Granted	128,255	1.89		
Cancelled	(100,008)	1.37		
Outstanding at March 31, 2014	<u>3,880,504</u>	1.51	8.06	18,555
Exercisable at December 31, 2013	<u>1,530,134</u>	1.09	6.70	5,216
Vested or expected to vest at December 31, 2013	<u>3,436,934</u>	1.45	8.06	10,427
Exercisable at March 31, 2014	<u>1,641,933</u>	1.12	6.60	8,482
Vested or expected to vest at March 31, 2014	<u>3,446,506</u>	1.45	7.88	16,643

The weighted-average fair values of options granted in the years ended December 31, 2012 and 2013 and in the three month periods ending March 31, 2013 and 2014 were \$0.85, \$1.09,

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

\$0.77 and \$3.37 per share, respectively, and were calculated using the following estimated assumptions:

	Year Ended December 31,		Three Months Ended March 31,	
	2012	2013	2013	2014
Weighted-average risk-free interest rate	1.35%	1.68%	1.02%	2.04%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected volatility	64%	63%	64%	62%
Expected terms	6.25 - 10 years	5.77 - 6.08 years	6.08 years	6.02 - 6.08 years

The total fair values of stock options that vested during the years ended December 31, 2012 and 2013 and during the three months ended March 31, 2013 and 2014 were \$302,000, \$476,000, \$219,000 and \$137,000, respectively, and \$1,355,000 for the cumulative period from April 27, 2006 (inception) to March 31, 2014.

**Restricted Stock**

In May 2006, the Company authorized the sale of 1,800,000 shares of restricted common stock to its six founders for \$0.01 per share, for total proceeds of \$18,000, which represented the fair market value of the Company's common stock as determined by management and the board of directors on the date of issuance. The sale agreements are dated June 25, 2006. These awards of restricted common stock were made outside of the 2006 Stock Option Plan. In the event of termination of the founders' relationship with the Company, the Company has the right to repurchase any unvested shares at their original purchase price. On July 25, 2006, 450,000, or 25% of the shares, were immediately vested. The remaining 75% of the shares vested over the next 36 calendar months and the Company's right to repurchase the shares lapsed at a rate of 2.777% per calendar month.

In March 2008, the Company issued 289,098 shares of restricted stock at \$0.28 per share to an executive of the Company for a total purchase price of \$81,000. The shares vested over a four-year period.

At December 31, 2013, all restricted shares were vested and no longer subject to repurchase and are considered outstanding on the Company's statement of redeemable convertible preferred stock and stockholders' (deficit) equity.

**T2 Biosystems, Inc.**  
**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

**Stock-Based Compensation Expense**

The following table summarizes the stock-based compensation expense for stock options granted and restricted stock issued to employees and nonemployees that was recorded in the Company's results of operations for the years ended December 31, 2012 and 2013, and for the period from April 27, 2006 (inception) to December 31, 2013 (in thousands):

	Year Ended December 31,		Three Months Ended March 31,		Period From April 27, 2006 (Inception) to March 31, 2014
	2012	2013	2013	2014	2014
Research and development	\$ 160	\$ 169	\$ 46	\$ 56	\$ 700
Selling, general and administrative	243	409	76	183	1,450
<b>Total stock-based compensation expense</b>	<b>\$ 403</b>	<b>\$ 578</b>	<b>\$ 122</b>	<b>\$ 239</b>	<b>\$ 2,150</b>

As of December 31, 2013 and March 31, 2014, there was \$2,247,000 and \$2,447,000 of total unrecognized compensation cost related to non-vested stock options granted under the 2006 Stock Option Plan. Total unrecognized compensation cost will be adjusted for future changes in the estimated forfeiture rate. The Company expects to recognize that cost over a remaining weighted-average period of 3.06 years and 3.03 years as of December 31, 2013 and March 31, 2014, respectively.

**10. Warrants**

Below is a summary of warrants outstanding as of the dates presented:

	December 31,		March 31,
	2012	2013	2014
Warrants to purchase Series A-2 preferred stock	13,769	13,769	13,769
Warrants to purchase Series B preferred stock	187,178	187,178	187,178
Warrants to purchase Series C preferred stock	30,000	30,000	30,000
Warrants to purchase Series D preferred stock	19,780	19,780	19,780
<b>Total warrants to purchase preferred stock</b>	<b>250,727</b>	<b>250,727</b>	<b>250,727</b>

In August 2007, the Company issued warrants to purchase 13,769 shares of series A-2 preferred stock to a lender at an exercise price of \$2.905 per share. At issuance, the warrants had a fair value of \$2.3238 per share. The warrants were issued in connection with the Company's secured notes payable (See Note 6). The warrants are exercisable through 2017.

In September 2008, the Company issued warrants to purchase 174,530 shares of series B preferred stock at an exercise price of \$3.3232 and 3,612 shares of series B preferred stock at an exercise price of \$4.65 in connection with a development agreement (See Note 12). At issuance,



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**Notes to Financial Statements (Continued)**

**10. Warrants (Continued)**

the warrants for 174,530 and 3,612 shares had a fair value of \$2.3219 and \$2.1348 per share, respectively. The warrants for 174,530 shares become exercisable on a pro rata basis as payments are received on Phase I of the development agreement. The warrants for 3,612 shares become exercisable on a pro rata basis as payments are received on Phase II of the development agreement. The warrants are exercisable through 2015. Any unexercised warrants will expire upon an initial public offering.

In June 2009, the Company issued warrants to purchase 9,036 shares of series B preferred stock to a lender at an exercise price of \$3.3232 per share. At issuance, the warrants had a fair value of \$2.6695 per share. The warrants were issued in connection with the Company's loan modification agreement related to Note Agreement 1 (See Note 6). The warrants are exercisable through 2019.

In May 2011, the Company issued warrants to purchase 30,000 shares of series C preferred stock to a lender at an exercise price of \$3.6608 per share. At issuance, the warrants had a fair value of \$2.9273 per share. The warrants were issued in connection with the Company's promissory note agreement related to Note Agreement 2 (See Note 6). The warrants are exercisable through 2021. The warrants automatically convert into shares of common stock upon an initial public offering in accordance with a net exercise formula.

In June 2012, the Company issued warrants to purchase 19,780 shares of series D preferred stock to a lender at an exercise price of \$4.55 per share. At issuance, the warrants had a fair value of \$3.2451 per share. The warrants were issued in connection with the Company's promissory note agreement related to Note Agreement 3 (See Note 6). The warrants are exercisable through 2022.

No warrants have been exercised as of December 31, 2013 and March 31, 2014.

Below is a summary of the terms and accounting treatment for the warrants outstanding:

	Shares	Weighted-Average Exercise Price Per Share	Balance Sheet Classification		
			December 31,		March 31,
			2012	2013	2014
Warrants to purchase Series A-2 preferred stock	13,769	\$ 2.91	Liability	Liability	Liability
Warrants to purchase Series B preferred stock	187,178	3.76	Liability	Liability	Liability
Warrants to purchase Series C preferred stock	30,000	3.66	Liability	Liability	Liability
Warrants to purchase Series D preferred stock	19,780	4.55	Liability	Liability	Liability
	250,727				

The Company determined the fair value of the warrants to purchase redeemable convertible preferred stock based on input from management and the board of directors, which utilized an independent valuation of the Company's enterprise value, determined utilizing an analytical valuation model. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions affecting the *in vitro* diagnostics industry sector, the prices at which the Company sold shares of preferred stock, the superior rights and

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**10. Warrants (Continued)**

preferences of securities at the time and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of the Company. Any changes in the assumptions used in the valuation could materially affect the financial results of the Company. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The analytical valuation model used for the years ended December 31, 2012 and 2013 and the three months ended March 31, 2014 are as follows:

	<b>Analytical Valuation Model Used</b>
December 31, 2012	Option Pricing Model (OPM)
December 31, 2013	Hybrid approach based on an OPM method and the Probability Weighted Expected Return Method (PWERM)
March 31, 2014	Hybrid approach based on an OPM method and the PWERM

**11. Net Loss Per Share**

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders (in thousands, except share and per share data):

	<b>Year Ended December 31,</b>		<b>Three Months Ended March 31,</b>		<b>Period From April 27, 2006 (Inception) to March 31, 2014</b>
	<b>2012</b>	<b>2013</b>	<b>2013</b>	<b>2014</b>	<b>2014</b>
<b>Numerator:</b>					
Net loss	\$ (14,455)	\$ (20,610)	\$ (4,580)	\$ (6,920)	\$ (79,181)
Accretion of redeemable convertible preferred stock to redemption value	(4,412)	(6,908)	(1,176)	(1,906)	(21,307)
Net loss applicable to common stockholders	<u>\$ (18,867)</u>	<u>\$ (27,518)</u>	<u>\$ (5,756)</u>	<u>\$ (8,826)</u>	<u>\$ (100,488)</u>
<b>Denominator:</b>					
Weighted-average number of common shares outstanding — basic and diluted	<u>2,314,832</u>	<u>2,372,542</u>	<u>2,346,601</u>	<u>2,400,422</u>	<u>1,714,171</u>
Net loss per share applicable to common stockholders — basic and diluted	<u>\$ (8.15)</u>	<u>\$ (11.60)</u>	<u>\$ (2.45)</u>	<u>\$ (3.68)</u>	<u>\$ (58.62)</u>

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**11. Net Loss Per Share (Continued)**

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because their effect would have been anti-dilutive for the periods presented:

	Year Ended December 31,		Three Months Ended March 31,		Period from April 27, 2006 (Inception) to March 31,
	2012	2013	2013	2014	2014
Redeemable convertible preferred stock	14,346,755	21,277,722	21,277,722	21,277,722	21,277,722
Options to purchase common shares	2,378,501	3,852,257	2,363,001	3,880,504	3,880,504
Warrants to purchase redeemable convertible preferred stock	250,727	250,727	250,727	250,727	250,727
Total	<u>16,975,983</u>	<u>25,380,706</u>	<u>23,891,450</u>	<u>25,408,953</u>	<u>25,408,953</u>

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**11. Net Loss Per Share (Continued)**

The following table presents the calculation of basic and diluted pro forma net loss per share applicable to common stockholders (in thousands, except share and per share data):

	<b>Year Ended December 31, 2013</b>	<b>Three Months Ended March 31, 2014</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
<b>Numerator:</b>		
Net loss applicable to common stockholders	\$	\$
Accretion of redeemable convertible preferred stock to redemption value		
Change in fair value of liability for warrants to purchase redeemable securities		
Pro forma net loss applicable to common stockholders (unaudited)	<u>\$</u>	<u>\$</u>
<b>Denominator:</b>		
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders — basic and diluted		
Pro forma adjustment to reflect assumed conversion of redeemable convertible preferred stock to occur upon consummation of initial public offering (unaudited)		
Pro forma adjustment to reflect assumed net exercise of warrants to purchase redeemable convertible preferred stock to occur upon consummation of initial public offering (unaudited)		
Pro forma weighted-average number of common shares used in computing pro forma net loss per share applicable to common stockholders — basic and diluted (unaudited)		
Pro forma net loss per share applicable to common stockholders — basic and diluted (unaudited)	<u>\$</u>	<u>\$</u>

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**12. Development Agreement**

In September 2008, the Company entered into a development agreement with a third party, whereby the third party: (i) invested \$300,000 through the purchase of 90,274 shares of series B preferred stock, (ii) received a warrant for the purchase of up to 178,142 shares of series B preferred stock at exercise prices of \$3.3232 and \$4.65, and (iii) agreed to pay the Company up to \$2,500,000 for the development of certain products as defined in the development agreement. The development work under the development agreement included two potential phases, with Phase 2 dependent to occur only on the election of the third party. Phase I was initiated on October 31, 2008. The Company received payments and recognized revenue of \$1,450,000 related to Phase I during the year ended December 31, 2009 under the proportional performance method. During 2012, the Company received and recognized as revenue an additional \$100,000 from the third party. The third party did not elect to proceed with Phase 2 of the development agreement.

The fair market value of the warrants issued in connection with the development agreement was recognized as an offset to revenue as the revenue associated with the development agreement was recognized. The value of the warrants was recorded as a deferred charge that was proportionally offset against revenue earned over the development period through 2012. The Company recognized \$81,000, and \$598,000 as an offset to revenue associated with these warrants for the year ended December 31, 2012 and for the period from April 27, 2006 (inception) to March 31, 2014, respectively.

**13. Income Taxes**

In 2012 and 2013, the Company did not record a benefit for income taxes related to its operating losses incurred since inception. In assessing the ability to realize the net deferred tax assets, management considered whether it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Based upon the level of historical U.S. losses and future projections over the period in which the net deferred tax assets are deductible, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2012 and 2013. The increase in the valuation allowance from 2012 to 2013 of \$9.0 million principally related to the current year taxable loss.

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**13. Income Taxes (Continued)**

The reconciliation of the U.S. federal statutory rate to the Company's effective tax rate is as follows:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2012</b>	<b>2013</b>
Tax at statutory rates	34.0%	35.0%
State income taxes	5.3	5.2
Change in tax rate	(0.2)	0.0
Permanent differences	(0.5)	(0.7)
Research and development credits	1.6	2.3
Change in valuation allowance	(40.2)	(41.8)
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>

The significant components of the Company's deferred tax asset consist of the following at December 31, 2012 and 2013 (in thousands):

	<b>December 31,</b>	
	<b>2012</b>	<b>2013</b>
Net operating loss carryforwards	\$ 14,184	\$ 22,280
Tax credits	1,318	2,189
Other temporary differences	49	180
Start-up expenditures	5,449	5,318
Stock option expenses	70	179
Net deferred tax assets	<u>21,070</u>	<u>30,146</u>
Deferred tax asset valuation allowance	<u>(21,070)</u>	<u>(30,146)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2013, the Company had federal and state net operating losses of \$56,036,828 and \$51,405,945, respectively, which are available to offset future taxable income, if any, through 2023. The Company also had federal and state research and development tax credits of \$1,738,000 and \$694,000, respectively, which expire at various dates beginning in 2016 through 2023.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately

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**Notes to Financial Statements (Continued)**

**13. Income Taxes (Continued)**

prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. The Company has not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

The Company has no unrecognized tax benefits. The Company has not conducted a study of its net operating loss carryforwards or its research and development credit carryforwards. A study could result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts will be presented as an uncertain tax position under ASC 740-10. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations if an adjustment were required. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statements of operations. At December 31, 2012 and 2013, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the U.S. federal tax jurisdiction and various state jurisdictions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The open tax years subject to future audit in the United States of America are for the years ended December 31, 2010 through 2012. The Company does not have any international operations through December 31, 2013.

**14. Commitments and Contingencies**

In August 2010, the Company entered into a five-year, noncancelable operating lease for office and laboratory space. The Company has the option to extend the lease for one additional term of two years. The lease commenced on January 1, 2011, with the Company providing a security deposit of \$400,000. In accordance with the operating lease agreement, the Company reduced its security deposit by \$80,000 to \$320,000 on January 14, 2013.

On May 1, 2013, the Company entered into a six month operating lease for laboratory space with an option to extend the lease an additional six months. In September 2013, the Company exercised the extension.

On May 6, 2013, the Company entered into a two-year operating lease for additional office, laboratory and manufacturing space.

**T2 Biosystems, Inc.**  
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**Notes to Financial Statements (Continued)**

**14. Commitments and Contingencies (Continued)**

Future minimum lease payments under the Company's three operating leases are as follows (in thousands):

Year ending December 31,	
2014	\$ 649
2015	<u>624</u>
	<u>\$ 1,273</u>

Rent expense for the years ended December 31, 2012 and 2013 was \$558,000 and \$628,000, respectively, and for the three months ended March 31, 2013 and 2014 was \$140,000 and \$169,000, respectively, and for the period from April 27, 2006 (inception) to March 31, 2014 was \$2,122,000.

In 2006, the Company entered into a license agreement with a third party, pursuant to which the third party granted the Company an exclusive, worldwide, sublicenseable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes. The Company agreed to pay an annual license fee ranging from \$5,000 to \$25,000 for the royalty-bearing license to certain patents. For the years ended December 31, 2012 and 2013, and for the period from April 27, 2006 (inception) to December 31, 2013, the Company paid \$65,000, \$46,000 and \$521,000, respectively, for license fees and reimbursed patent costs under the agreement. The Company also issued a total of 84,678 shares of common stock pursuant to the agreement in 2006 and 2007, which were recorded at fair value at the date of issuance. The Company is required to make payments for achievement of certain regulatory milestones with respect to products and processes covered by the agreement of up to \$300,000 in the aggregate. The Company will be required to pay royalties on net sales of products and processes that are covered by patent rights licensed under the agreement at a percentage ranging in the low single digits, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses at a low double-digit percentage of specified gross revenue.

**15. Related-Party Transactions**

In June 2006, the board of directors voted to pay quarterly compensation to two of the Company's founders, who are also members of the board of directors, for their services to the Company. The annual compensation was initially \$0 and automatically increased to \$10,000 to \$40,000 upon the achievement of certain equity financing milestones, as defined in the consulting agreement. The total compensation expense for the years ended December 31, 2012 and 2013, for the three months ended March 31, 2013 and 2014 and the period from April 27, 2006 (inception) to March 31, 2014 was \$80,000, \$80,000, \$20,000, \$20,000 and \$405,000, respectively.

**16. 401(k) Savings Plan**

In March, 2008, the Company established a retirement savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees



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**Notes to Financial Statements (Continued)**

**16. 401(k) Savings Plan (Continued)**

of the Company who meet minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pretax basis. Company contributions to the 401(k) Plan may be made at the discretion of the board of directors. No contributions were made in the years ended December 31, 2012 and 2013, and for the three months ended March 31, 2013 and 2014.

**17. Subsequent Events**

The Company has completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2013 through the date this Registration Statement on Form S-1 was submitted to the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2013 and March 31, 2014, and events which occurred subsequently but were not recognized in the financial statements. The Company has concluded that no subsequent event has occurred that requires disclosure.

Shares

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Common Stock

**Goldman, Sachs & Co.**

**Morgan Stanley**

**Leerink Partners**

**Janney Montgomery Scott**

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Through and including \_\_\_\_\_, 2014 (the 25<sup>th</sup> day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with this offering described in this registration statement, other than the underwriting discount, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The NASDAQ Global Market fee.

	<u>Amount</u>
SEC Registration fee	\$ *
FINRA filing fee	*
NASDAQ Global Market initial listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	<u>\$ *</u>

\* To be provided by amendment

**Item 14. Indemnification of Directors and Officers.**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our restated certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation

unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our restated certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, or the Securities Act, against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuance of Securities.

1. In August 2011, we issued an aggregate of 5,054,945 shares of series D preferred stock to investors at a price per share of \$4.55 for aggregate gross consideration of \$23.0 million. These shares will automatically convert into 5,054,945 shares of our common stock upon the closing of this offering.

2. In March 2013, we issued an aggregate of 6,930,967 shares of series E preferred stock to investors at a price per share of \$5.7712 for aggregate gross consideration of \$40.0 million. These shares will automatically convert into 6,930,967 shares of our common stock upon the closing of this offering.

(b) Stock Option Grants. From January 1, 2011 through June 24, 2014, we granted stock options to purchase an aggregate of 3,504,304 shares of our common stock at a weighted-average exercise price of \$1.85 per share, to certain of our employees, directors and consultants in connection with services provided to us by such persons. Of these, options to purchase 71,793 shares of common stock have been exercised through June 24, 2014 for aggregate consideration of \$101,277, at a weighted-average exercise price of \$1.41 per share.

(c) Warrants. Since May 2011, we issued one warrant to SVB and one to MDF in connection with various loan and security agreements. These warrants are immediately exercisable for the purchase of 49,780 shares of preferred stock. If none of these warrants are exercised, upon the closing of this offering, SVB's warrant for 19,780 shares of preferred stock will terminate while MDF's warrant for the purchase of 30,000 shares of preferred stock will automatically convert to common stock pursuant to a cashless net exercise.

The issuances of stock options, warrants and the shares of common stock issuable upon the exercise of the options described in this Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities have not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
1.1*	Form of Underwriting Agreement
3.1**	Restated Certificate of Incorporation of the Registrant, as amended (currently in effect)
3.2**	Bylaws of the Registrant (currently in effect)
3.3*	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Amended and Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1*	Specimen Stock Certificate evidencing the shares of common stock
4.2**	Fourth Amended and Restated Investors' Rights Agreement, dated as of March 22, 2013
5.1*	Opinion of Latham & Watkins LLP
10.1##**	Amended and Restated 2006 Employee, Director and Consultant Stock Plan, as amended, and form of option agreements thereunder
10.2##*	2014 Incentive Award Plan and form of option agreements thereunder
10.3##*	Non-Employee Director Compensation Program
10.4*	Form of Indemnification Agreement for Directors and Officers
10.5##**	Employment Letter Agreement, dated as of March 14, 2008, by and between the Registrant and John McDonough
10.6##**	Employment Letter Agreement, dated as of March 8, 2013, by and between the Registrant and Marc Jones
10.7##**	Employment Letter Agreement, dated as of July 19, 2013, by and between the Registrant and Sarah Kalil
10.8##**	Employment Letter Agreement, dated as of February 15, 2014, by and between the Registrant and Michael Pfaller
10.9##**	Employment Letter Agreement, dated as of December 19, 2006, by and between the Registrant and Tom Lowery, Jr.
10.10##**	Consulting Agreement, dated as of July 20, 2006, by and between the Registrant and Michael Cima, as amended on March 19, 2013
10.11##**	Consulting Agreement, dated as of July 20, 2006 by and between the Registrant and Robert Langer, as amended on March 20, 2013
10.12†**	Sales Agreement, dated as of February 11, 2011, by and between GE Healthcare Bio-Sciences Corp. and the Registrant
10.13†**	Exclusive License Agreement, dated as of November 7, 2006, as amended on December 2, 2008 and February 21, 2011, by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and the Registrant

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
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10.14**	Security Agreement, dated as of May 9, 2011, by and between the Registrant and Massachusetts Development Finance Agency
10.15**	Loan and Security Agreement, dated as of August 30, 2007, as amended by the First Loan Modification Agreement on June 26, 2009 and the Second Loan Modification Agreement on June 25, 2013, by and between the Registrant and Silicon Valley Bank
10.16**	Lease, dated as of May 6, 2013, as amended on September 24, 2013, by and between the Registrant and Columbus Day Realty, Inc.
10.17**	Lease, dated as of August 6, 2010, by and between the Registrant and King 101 Hartwell LLC
10.18**	Promissory Note, dated May 9, 2011, issued by the Registrant to Massachusetts Development Finance Agency
23.1*	Consent of Ernst & Young LLP
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

\* To be filed by amendment.

\*\* Previously filed.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (4) In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.



**SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lexington, Commonwealth of Massachusetts, on this       day of       , 2014.

T2 BIOSYSTEMS, INC.

By: \_\_\_\_\_

John McDonough  
President and Chief Executive Officer

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## SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of T2 Biosystems, Inc., hereby severally constitute and appoint John McDonough and Marc R. Jones, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-1 has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ John McDonough	President, Chief Executive Officer and Director (principal executive officer)	, 2014
_____ Marc R. Jones	Chief Financial Officer (principal financial and accounting officer)	, 2014
_____ David B. Aronoff	Director	, 2014
_____ Joshua Bilenker, M.D.	Director	, 2014
_____ Thomas J. Carella	Director	, 2014
_____ Michael J. Cima, Ph.D.	Director	, 2014
_____ Alan Crane	Director	, 2014

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Signature

Title

Date

<hr/> Stacy A. Feld	Director	, 2014
<hr/> Robert Langer, D. Sc.	Director	, 2014
<hr/> Stanley N. Lapidus	Director	, 2014
<hr/> Harry W. Wilcox	Director	, 2014

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