Ignyta, Inc.
Form S-1
February 28, 2014
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As filed with the Securities and Exchange Commission on February 28, 2014

No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

IGNYTA, INC.

(Exact name of registrant as specified in its charter)

Nevada	**2834**	**59-3564984**
(State of Incorporation)	***(Primary Standard Industrial Classification Code Number)***	***(IRS Employer Identification No.)***

11095 Flintkote Avenue, Suite D

San Diego, California 92121

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

Jonathan E. Lim, M.D.

President and Chief Executive Officer

11095 Flintkote Avenue, Suite D

San Diego, California 92121

(858) 255-5959

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

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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, please 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. (Check one):

Large accelerated filer ¨ Accelerated filer ¨

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[(1)]	Amount of Registration Fee
Common Stock, $0.00001 par value per share	$46,000,000	$5,925

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of additional shares that the underwriters have the option to purchase.

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.

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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 preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 28, 2014

PRELIMINARY PROSPECTUS

$40,000,000

Common Stock

We are offering up to $40,000,000 of shares of our common stock.

Our common stock is quoted on the OTCQB Marketplace and the OTC Bulletin Board under the symbol RXDX. On , 2014, the last reported sale price for our common stock as reported on the OTCQB Marketplace was $ per share. After the pricing of this offering, we expect that our common stock will be listed on the NASDAQ Capital Market under the symbol RXDX.

Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page 8 of this prospectus for a discussion of factors you should consider before buying shares of our common stock.

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.

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

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us.	$	$

(1) Please refer to Underwriting on beginning on page 127 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters an option for 30 days to purchase up to $6,000,000 of additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions

payable by us will be $, and the total proceeds to us, before expenses, will be $.

Delivery of the shares of common stock will be made on or about , 2014.

Leerink Partners

Ladenburg Thalmann & Co.

The date of this prospectus is , 2014

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About This Prospectus

You should rely only on the information that we have provided or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus is accurate only as of the date on the front of this document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or

will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading Where You Can Find Additional Information.

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As used in this prospectus, unless the context indicates or otherwise requires, our company, we, us, and our refer to Ignyta, Inc., a Nevada corporation, and its consolidated subsidiary, and the term Ignyta Operating refers to Ignyta Operating, Inc., a private Delaware corporation that, through a reverse merger acquisition completed on October 31, 2013, became our wholly owned subsidiary.

Ignyta and Ignyta Operating effected reverse stock splits of their capital stock at the ratios of 100-to-one and three-to-one, respectively, on October 31, 2013. Unless the context indicates or otherwise requires, all share numbers and share price data included in this prospectus have been adjusted to give effect to those reverse stock splits.

We have registered trademarks for Ignyta®, Methylome®, Trailblaze® and Actagene®, and have a pending trademark application for Oncolome . All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Use or display by us of other parties trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

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PROSPECTUS SUMMARY

This summary does not contain all of the information that should be considered before investing in our common stock. Investors should carefully read this prospectus, and the registration statement of which this prospectus is a part, in their entirety before investing in our common stock, including the information discussed under Risk Factors in this prospectus.

Our Company

Overview

We are a precision medicine biotechnology company dedicated to discovering or acquiring, then developing and commercializing, precisely targeted new drugs for cancer patients whose tumors harbor specific molecular alterations. We are pursuing an integrated drug and diagnostic, or Rx/Dx, strategy, where we anticipate pairing each of our product candidates with biomarker-based companion diagnostics, developed by us or by third parties with which we may partner, that are designed to identify the patients that are most likely to benefit from the use of the drugs we may develop. Our current development plans focus on two product candidates: RXDX-101, a tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in a Phase I/II clinical study in molecularly defined patient populations for the treatment of solid tumors; and RXDX-102, a tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors. As a result of the preliminary Phase I results relating to RXDX-101 that we have seen to date, we have decided to designate RXDX-102 as a back-up compound to RXDX-101. Accordingly, we will not devote further development resources to RXDX-102 unless the development program for RXDX-101 is unsuccessful. We have entered into a license agreement with Nerviano Medical Sciences S.r.l., or NMS, granting us exclusive global development and marketing rights to RXDX-101 and RXDX-102, which became effective on November 6, 2013. We also have three discovery stage programs, Spark-1, Spark-2 and Spark-3, directed to emerging oncology targets identified through mining of our database of information from proprietary and publicly available tumor samples, called Oncolome.

Our business is focused on discovering novel biomarkers that define diseases based on our belief that such biomarkers could provide rich biological insight into the underlying pathophysiology that drives the clinical symptomatology of those diseases. Biomarkers are substances detectable in the human body that can indicate presence or risk of a certain disease or disease subtype. One of our core platforms for revealing multivariate biomarkers that characterize diseases of interest is epigenetic analysis, particularly assessment of DNA methylation signatures. Epigenetics is the study of heritable changes in gene activity that are not caused by changes in DNA sequence, and DNA methylation is a specific type of epigenetic phenomenon that involves the chemical addition of a methyl group to DNA, which addition can impact the activity of that gene. A methylation signature is a specific pattern of differential DNA methylation that can serve as a biomarker that is indicative of a certain disease or disease subtype. When individual DNA sites have a different presence or absence of methyl groups in one individual compared to another individual or group of individuals, we refer to this as differential methylation.

Our current focus is to identify genes and pathways that are altered in tumors of interest and to then acquire or develop drugs that target the proteins encoded by those genes and test those drugs in precise patient populations who have the underlying molecular alteration that our product candidates seek to address. Our strategy is to leverage the biomarker insights that we gain through our genetic and epigenetic mining of our Oncolome database and the knowledge of cancer biology of our management and drug discovery team, with the goal of discovering or acquiring, validating, developing and commercializing a pipeline of novel product candidates for the treatment of cancer.

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We currently have no products that have obtained marketing approval in any jurisdiction. We have not generated revenues since inception and do not expect to do so in the foreseeable future due to the early stage nature of our current product candidates. We had net losses for the year ended December 31, 2013 of $14.2 million, and we had an accumulated deficit as of December 31, 2013 of $15.6 million.

For more information regarding our business, see the disclosure under the headings Management s Discussion and Analysis of Financial Condition and Results of Operations and Business included elsewhere in this prospectus.

Our Strategy

Our goal is to become a leading precision medicine oncology company by developing the next generation of therapeutics that treat cancer by targeting specific oncogenic activating molecular alterations and the corresponding patient populations. We believe our competitive advantage lies at the nexus of our two fundamental approaches: (1) a bottom up, data driven, unbiased, genome-wide multi-omics (e.g., DNA sequence, DNA methylation, DNA expression and protein expression) approach to mining extensive tumor data to identify activating alterations and their key biomarkers; and (2) a top down drug hunter approach of applying our senior scientific leadership team s many decades of successful cancer drug discovery and development experience. Key elements of our strategy are to:

- Utilize public and proprietary sources of tumor samples and cancer data so that we are informed by a rich knowledge base.
- Apply a multi-omics approach to discover activating molecular alterations that drive cancer biology.
- Leverage deep cancer biology expertise and systems biology understanding to identify the specific role of activating alterations.
- Deploy drug design tools to develop small molecule inhibitors of activating targets.
- Employ a capital-efficient drug development team.
- Test our product candidates only in the patients that we believe are most likely to derive benefit.
- Develop, or pursue relationships with third parties to develop, companion diagnostics to assist in identifying appropriate patients for any product candidates we are able to successfully commercialize.
- In-license development candidates that meet our strict criteria.

Seek and maintain commercial rights and, when and if appropriate, establish commercialization and marketing capabilities.

Risks Associated with Our Business

Our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled Risk Factors in this prospectus, as well as the other risks described in Risk Factors.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a development-stage company with no approved products, and have generated no revenue to date and may never generate revenue or achieve profitability.

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We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.

We are heavily dependent on the success of our lead product candidate, which will require significant additional efforts to develop and may prove not to be viable for commercialization.

Our research and development is based on a rapidly evolving area of science, and our approach to drug discovery and development is novel and may never lead to marketable products.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and any of our clinical trials or studies could produce unsuccessful results or fail at any stage in the testing process.

If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

The approval processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business will be substantially harmed.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy and operational results.

We rely on third parties to conduct preclinical and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.

The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.

We will need to grow the size of our organization, and we may experience difficulties in managing any growth we may achieve.

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.

Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control.

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We may be exposed to additional risks as a result of going public by means of a reverse merger transaction.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Corporate Information

Ignyta was incorporated under the laws of the State of Nevada on August 21, 2012, with the name Infinity Oil & Gas Company. Ignyta Operating was incorporated under the laws of the State of Delaware on August 29, 2011, with the name NexDx, Inc. and changed its name to Ignyta, Inc. on October 8, 2012. On October 31, 2013, IGAS Acquisition Corp, a wholly owned subsidiary of Ignyta, merged with and into Ignyta Operating, and Ignyta Operating survived the merger and became our wholly owned subsidiary. Upon the closing of the merger, we ceased to be a shell company under applicable rules of the Securities and Exchange Commission, or the SEC. In connection with the closing of the merger, Ignyta changed its name to Ignyta, Inc. and Ignyta Operating changed its name to Ignyta Operating, Inc. Our principal executive offices are located at 11095 Flintkote Avenue, Suite D, San Diego, California 92121, and the telephone number at our principal executive office is (858) 255-5959. Our website address is http://www.ignyta.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which was on February 15, 2013; (ii) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before December 31, 2018. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act, and references herein to emerging growth company have the meaning associated with it in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified 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 requirement of auditor attestation of our internal controls 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

not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

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For as long as we continue to be an emerging growth company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of that classification. We have taken advantage of certain of reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.

We are also a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies.

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The Offering

Common stock offered by us	$40,000,000 of shares of common stock
Common stock to be outstanding after this offering	shares
Option to purchase additional shares	The underwriters have an option for a period of 30 days to purchase up to $6,000,000 of additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering to fund the development of our lead product candidate, RXDX-101, and for other research and development of our other product candidates, working capital and general corporate purposes. See Use of Proceeds for a more complete description of the intended use of proceeds from this offering.
Risk factors	Investing in our securities involves a high degree of risk and purchasers may lose their entire investment. You should read the Risk Factors section of this prospectus for a discussion of certain factors to consider carefully before deciding to purchase any shares of our common stock.
Proposed NASDAQ Capital Market symbol	RXDX

The number of shares of our common stock to be outstanding after this offering is based on 13,934,876 shares of common stock outstanding as of December 31, 2013, and assumes the sale of $40,000,000 of shares of common stock at $ per share, the last reported sale price for our common stock as reported on the OTCQB Market Place, or the OTCQB, on , 2014. A 5% increase or decrease in the assumed public offering price of $ per share would increase or decrease the number of shares of our common stock issued in this offering by approximately 5%. The number of shares of our common stock to be outstanding after this offering excludes:

1,133,153 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2013, at a weighted average exercise price of $4.33 per share;

41,668 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2013, at a weighted average exercise price of $4.20 per share;

1,567,209 shares of common stock reserved for future issuance under our Amended and Restated 2011 Stock Incentive Plan, or the Ignyta Plan, as of December 31, 2013; and

the exercise by us of a contractual right to repurchase 400,000 shares of restricted common stock in February 2014 in connection with the departure of an employee.

Unless otherwise indicated, all information contained in this prospectus, and the number of shares of common stock outstanding as of December 31, 2013, assumes no exercise by the underwriters of their option to purchase up to an additional $6,000,000 of shares of our common stock.

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Summary Consolidated Financial Data

The following tables summarize our consolidated financial data for the periods presented and should be read together with the sections of this prospectus entitled Risk Factors, Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as our consolidated financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statement of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results we expect in the future.

	Year Ended December 31,	
	2013	2012
	(audited)	
Consolidated Statements of Operations Data:		
Revenue	$	$
Expenses		
Research and development	10,170,866	708,043
General and administrative	3,730,941	547,882
Loss from operations	(13,901,807)	(1,255,925)
Other expense	(309,741)	(22,619)
Loss before income taxes	(14,211,548)	(1,278,544)
Income tax provision	2,095	1,308
Net loss	$ (14,213,643)	$ (1,279,852)
Basic and diluted loss per share of common stock	$ (3.83)	$ (2.00)
Weighted average number shares outstanding	3,711,885	640,364

The unaudited pro forma balance sheet data set forth below give effect to our issuance and sale of $40,000,000 of shares of our common stock in this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2013	
	Actual (audited)	Pro Forma (unaudited)
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 51,803,716	$
Total assets	53,318,840	
Total liabilities	11,531,235	
Deficit accumulated during the development stage	(15,572,940)	

Total stockholders equity	41,787,605

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes, before making any decision to invest in shares of our common stock. This prospectus contains forward-looking statements. If any of the events discussed in the risk factors below occurs, our business, prospects, results of operations, financial condition and cash flows could be materially harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a development-stage company with no approved products, and have generated no revenue to date and may never generate revenue or achieve profitability.

We are a development-stage biopharmaceutical company with a limited operating history. We have not generated any revenue to date and are not profitable, and have incurred losses in each year since our inception. Our net loss for the year ended December 31, 2013 was $14.2 million. As of December 31, 2013, we had an accumulated deficit of $15.6 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are currently focused primarily on the development of RXDX-101, Spark-1, Spark-2 and Spark-3, which we believe will result in our continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of our products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital.

We will need substantial additional funding to continue our operations, which could result in significant dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.

Our operations have consumed substantial amounts of cash since inception. We expect to need substantial additional funding to pursue the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, which may include building internal sales and marketing forces to address certain markets.

On November 6, 2013, we closed a private placement of our common stock for gross proceeds to us of approximately $46.4 million, and on November 29, 2013, we closed a subsequent private placement of our common stock for gross proceeds to us of approximately $7.6 million. In addition, on December 31, 2013, we received aggregate funding of $10 million, representing the full principal amount under a loan from Silicon Valley Bank, or SVB. Even after giving effect to the proceeds received from the private placements, the loan from SVB and the proceeds of this offering, we will require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly

than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the ongoing

development of RXDX-101 and other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and/or cause us to spend our cash resources faster than we expect. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

To date, we have financed our operations entirely through equity investments by founders and other investors and the incurrence of debt, and we expect to continue to do so in the foreseeable future. We may also seek funding through collaborative arrangements. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. For instance, in connection with the closing of the private placements on November 6, 2013 and November 29, 2013, we issued an aggregate of 9,010,238 shares of our common stock, which equaled approximately 66.62% of our issued and outstanding capital stock as of February 28, 2014. If we raise additional capital through the incurrence of further indebtedness, as we have done with our loan from SVB and under which our ability to incur additional indebtedness is limited, we would likely become subject to additional covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of the revenues associated with the partnered product.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Any of these events could significantly harm our business, financial condition and prospects.

Our short operating history may hinder our ability to successfully meet our objectives, and may limit the amount of information about us upon which you can base an evaluation of our business and prospects.

Our initial focus was on the discovery and development of biomarkers and molecular and companion diagnostic tests for certain autoimmune diseases. Only since May 2013 have we focused our business on precision medicines for the treatment of cancers. Consequently, we have limited experience operating this business and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Further, the early stage nature of our business results in a limited operating history upon which you can evaluate our business and prospects. Our lead product candidates are in the earliest stages of development, have not obtained regulatory marketing approval, have never generated any sales and will require extensive testing before commercialization. Our limited operating history may adversely affect our ability to implement our business strategy and achieve our business goals, which include, among others, the following activities:

- develop our product candidates using unproven technologies;

obtain the human and financial resources necessary to develop, test, manufacture and market our product candidates;

engage corporate partners to assist in developing, testing, manufacturing and marketing our product candidates;

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- continue to build and maintain an intellectual property portfolio covering our technology and our product candidates;
- satisfy the requirements of clinical trial protocols, including patient enrollment, establish and demonstrate the clinical efficacy and safety of our product candidates and obtain necessary regulatory approvals;
- market our product candidates that receive regulatory approvals to achieve acceptance and use by the medical community in general;
- maintain, grow and manage our internal teams as and to the extent we increase our operations and develop new segments of our business;
- develop and maintain successful collaboration, strategic and other relationships for the development and commercialization of our product candidates and those of our partners that receive regulatory approvals; and
- manage our cash flows and any growth we may experience in an environment where costs and expenses relating to clinical trials, regulatory approvals and commercialization continue to increase.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

We have incurred significant indebtedness under our loan agreement with SVB, which will require substantial cash to service and which subjects our business to certain restrictions.

On December 31, 2013, we incurred $10 million of indebtedness at an interest rate of 6.92% under an amended and restated loan agreement with SVB. We are obligated to make payments under the loan agreement in 36 equal monthly installments following a 12-month period of interest-only payments, and we expect our interest payment obligations thereunder to total approximately $644,000 for our 2014 fiscal year. Further, the terms of the loan agreement require that we make a final lump-sum payment of $1,050,000, equal to 10.5% of the principal amount of the loan thereunder, upon the maturity date of such loan on December 1, 2017. Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Additionally, the loan agreement contains various covenants, including an obligation to deliver to SVB certain financial and insurance information and comply with certain notice requirements, and covenants that restrict our ability, without SVB s prior consent, to: replace our chief executive officer; incur certain additional indebtedness; enter into certain mergers, acquisitions or other business combination transactions; or incur any non-permitted lien or other encumbrance on our assets. Any failure by us to comply with any of those covenants, subject to certain cure periods, or to make all payments under the loan agreement when due, would cause us to be in default under the loan agreement. In the event of any such default, SVB may be able to declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our

available cash to be used to repay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

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Risks Related to our Employees

If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy. Our Chief Scientific Officer recently resigned from his positions with us.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified personnel. We are highly dependent on our management, scientific and medical personnel, especially Jonathan E. Lim, our President, Chief Executive Officer and Chairman of the Board, whose services are critical to the successful implementation of our product candidate development and regulatory strategies. Further, as our approach is built in part upon the drug discovery and development experience of our scientific drug hunter team, which we believe is a significant contributor to our competitive advantage, we are dependent on the maintenance and growth of that team with qualified members containing high levels of expertise in specific scientific fields.

In January 2014, Patrick O Connor, who had been on a medical leave of absence since September 2, 2013, informed us that the state of his health would not allow him to return to his positions as our Senior Vice President, Research, and Chief Scientific Officer, and he resigned from employment with us effective February 5, 2014. Dr. O Connor joined us in May 2013 after Ignyta Operating acquired Actagene, a discovery stage precision medicine company that Dr. O Connor founded in February 2013. Prior to that, Dr. O Connor had served as the chief scientific officer or in comparable positions for several public and private biotechnology companies and assisted in the development of several U.S. Food and Drug Administration, or FDA, approved drugs. Dr. O Connor was a valuable member of our scientific and drug discovery team, and his departure could cause our operations and prospects to suffer.

Except as described in the preceding paragraph, we are not aware of any present intention of any of our executive officers or other members of management to leave our company. However, our industry tends to experience a high rate of turnover of management personnel and our personnel are generally able to terminate their relationships with us on short notice. All of our employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Additionally, several members of our scientific team are consultants rather than employees, and could terminate their consulting relationship with us at any time or with short notice, depending on the terms of their respective consulting agreements with us. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior and mid-level managers as well as junior and mid-level scientific and medical personnel.

Moreover, there is intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles, longer histories in the industry and greater ability to provide valuable cash or stock incentives to potential recruits than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we are able to offer as an early-stage company. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, with contractual provisions and

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other procedures, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee s former employers. Litigation may be necessary to defend against any such claims.

On June 19, 2013, we received a letter from legal counsel for Ruga Corporation, a private oncology biopharmaceutical company for which some of our current employees and consultants previously provided services, making certain allegations regarding use of its proprietary synthetic lethal screening technology and certain related claims. We investigated each of those claims and we believe them to be wholly without merit. On August 15, 2013, we responded to the letter from Ruga Corporation s legal counsel, describing the results of our investigation and denying each claim made. We subsequently provided certain information to Ruga Corporation s legal counsel, who has not responded to us. We have received no communication from Ruga Corporation or its counsel since September 26, 2013. We would vigorously defend any claims that may be pursued relating to this matter.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with regulations of governmental authorities, such as the FDA or the European Medicines Agency, or EMA, to provide accurate information to the FDA or EMA, to comply with manufacturing standards we have established, to comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we currently take and the procedures we may establish in the future as our operations and employee base expand to detect and prevent this type of 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 by our employees to comply with such 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 and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our lead product candidate, which will require significant additional efforts to develop and may prove not to be viable for commercialization.

To date, we have invested significant efforts in the acquisition of our two product candidates from NMS. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize RXDX-101, with RXDX-102 as a back-up compound in case the development of RXDX-101 is not successful. Our business depends entirely on the successful development, clinical testing and commercialization of these and any other product candidates we may seek to develop in the future, which may never

occur.

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Before we could generate any revenues from sales of our lead product candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete:

- conduct substantial additional clinical development;
- manage clinical, preclinical and manufacturing activities;
- achieve regulatory approval in multiple jurisdictions;
- establish manufacturing relationships for the supply of the applicable product candidate;
- build a commercial sales and marketing team, if we choose to market any such product ourselves;
- develop and implement marketing strategies;
- develop and/or work with third-party collaborators to develop companion diagnostics and conduct clinical testing and achieve regulatory approvals for those companion diagnostics; and
- invest significant additional cash in each of the above activities.

If the results of the ongoing RXDX-101 Phase I/II clinical trial are not successful, we may not be able to use those results as the basis for advancing the product candidate into further clinical development. In that case, we may not have the resources to conduct new clinical trials, and/or we may determine that further clinical development of this product candidate is not justified and may decide to discontinue the program. Clinical testing of RXDX-102 would not commence unless the development of RXDX-101 is not successful, but the results of any future preclinical studies or clinical trials of RXDX-102, if unsuccessful, could lead to our abandonment of the development of that product candidate as well. If studies of these product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed.

Preclinical and clinical testing of our lead product candidates that has been conducted to date may not have been performed in compliance with applicable regulatory standards, which could lead to increased costs or material delays for their further development.

We have only recently licensed the rights to develop our two product candidates from NMS, and the development of those product candidates prior to our license was conducted wholly by NMS or any third parties with which it had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. We have only recently assumed full control of preclinical studies and clinical trials relating to those product candidates. However, because we had no input on NMS s development activities relating to these product candidates prior to us assuming full control, we may discover that all or certain elements of the trials and studies it has previously performed have not been in compliance with applicable regulatory standards or have otherwise been deficient. For

instance, the development of each of these product candidates to date has been conducted only in Europe. As a result, although we may find that those studies meet the standards of applicable European regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable FDA standards to allow immediate further development of those product candidates in the United States, and also may not meet the standards of applicable regulatory authorities in any non-European foreign country in which we desire to pursue marketing approval for these product candidates. If the studies conducted to date have not been in full compliance with applicable regulatory standards or are otherwise not eligible for continued development in the United States, then we may be forced to conduct new studies in order to progress their development, which we may not have the funding or other resources to complete and which would severely delay any of our development plans for these product candidates. Any such deficiency in the prior development of these product candidates would significantly harm our business plans and prospects.

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Our research and development is based on a rapidly evolving area of science, and our approach to drug discovery and development is novel and may never lead to marketable products.

Biopharmaceutical product development is generally a highly speculative undertaking and by its nature involves a substantial degree of risk. Our specific line of business, the discovery of personalized drug therapeutics for patients with molecularly defined cancers, is an emerging field, and the scientific discoveries that form the basis for our efforts to develop product candidates are relatively new. Further, the scientific evidence to support the feasibility of developing product candidates based on those discoveries is both preliminary and limited. Although epigenetic regulation of gene expression plays an essential role in biological function, very few drugs premised on epigenetics have been discovered. Moreover, drugs based on an epigenetic mechanism that have received marketing approval are not targeted to differentially methylated genes, which is the focus of some of our epigenetic research and development. As a result, identifying drug targets based in part on differential gene methylation may not lead to the discovery or development of any drugs that successfully treat patients with molecularly defined cancers. The failure of the scientific underpinnings of our business model to produce viable product candidates would substantially harm our operations and prospects.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to use and expand our product platform to build a pipeline of inhibitors of genetically and epigenetically altered targets, and progress those product candidates through clinical development for the treatment of a variety of different types of cancer. Although our research efforts to date have resulted in identification of a series of genetically or epigenetically altered cancer drug targets, we may not be able to develop product candidates that are safe and effective inhibitors of all or any of these targets. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and any of our clinical trials or studies could produce unsuccessful results or fail at any stage in the testing process.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Additionally, any positive results of preclinical studies and early clinical trials of a product candidate may not be predictive of the results of later-stage clinical trials, such that product candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in initial clinical trials. For example, although the preclinical and early clinical results for our lead product candidate has been positive, those results and the results that may be generated in the ongoing Phase I/II clinical trial for RXDX-101 do not imply that later clinical trials will demonstrate similar results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. The results of any future clinical trials we conduct may not be successful.

Although there is a clinical trial ongoing for RXDX-101, we may experience delays in pursuing those or any other clinical or preclinical studies. Clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining regulatory approval to commence a trial;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

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obtaining approval from an independent institutional review board, or IRB, at each trial site;

enrolling suitable patients to participate in a trial;

developing and validating companion diagnostics on a timely basis;

changes in dosing or administration regimens;

having patients complete a trial or return for post-treatment follow-up;

clinical sites deviating from trial protocol or dropping out of a trial;

regulators instituting a clinical hold due to observed safety findings;

adding new clinical trial sites; or

manufacturing sufficient quantities of product candidate for use in clinical trials.

We currently rely, and we expect to continue to rely, on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have an agreement in place with a CRO governing its committed activities and conduct, and we expect we will have similar agreements with other CROs we may engage in the future, we have limited influence over their actual performance. As a result, we ultimately do not have control over a CRO s compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements, or its adherence to agreed time schedules and deadlines, and a future CRO s failure to perform those obligations could subject any of our clinical trials to delays or failure.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for the trial, if applicable, or by the FDA, EMA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we were to experience delays in the completion of, or suspension or termination of, any clinical trial for our product candidates, the commercial prospects of the product candidate would be harmed, and our ability to generate product revenues from the product candidate would be delayed or eliminated. In addition, any delays in completing clinical trials would increase our costs, slow down our product candidate development and approval process and jeopardize regulatory approval of the product candidate. The occurrence of any of these events could harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are focused on patients with molecularly defined cancers, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors product candidates.

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Patient enrollment for any of our clinical trials may also be affected by other factors, including without limitation:

- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, and we may not have or be able to obtain sufficient cash to fund such increased costs when needed, which could result in the further delay or termination of the trial.

Consistent with our general product development strategy, we intend to design the Phase II aspect of the ongoing Phase I/II clinical trial of RXDX-101 and any future trials for those or other product candidates to include some patients with the applicable molecular alteration that causes the disease, with a view to assessing possible early evidence of potential therapeutic effect. If we are unable to locate and include such patients in those trials, then our ability to make those early assessments and to seek participation in FDA expedited review and approval programs, including breakthrough therapy and fast track designation, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised.

The approval processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We have not submitted a New Drug Application, or NDA, or similar filing or obtained regulatory approval for any product candidate in any jurisdiction and it is possible

that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

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- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;

- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and

- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, RXDX-101 or any other product candidates we may seek to develop in the future, which would significantly harm our business, results of operations and prospects.

In order to market and sell our products in any jurisdiction, we or our third party collaborators must obtain separate marketing approvals in that jurisdiction and comply with its regulatory requirements. The approval procedure can vary drastically among countries, and each jurisdiction may impose different testing and other requirements to obtain and maintain marketing approval. Further, the time required to obtain those approvals may differ substantially among jurisdictions. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions. As a result, the ability to market and sell a product candidate in more than one jurisdiction can involve significant additional time, expense and effort to undertake separate approval processes, and would subject us and our collaborators to the numerous and varying post-approval requirements of each jurisdiction governing commercial sales, manufacturing, pricing and distribution of our product candidates. We or any third parties with whom we may collaborate may not have the resources to pursue those approvals, and we or they may not be able to obtain any approvals that are pursued. The failure to obtain marketing approval for our product candidates in foreign jurisdictions could severely limit their potential market and ability to generate revenue.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our product candidates.

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Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

To date, patients treated with RXDX-101 have experienced some drug-related adverse events, which have been predominantly gastrointestinal or constitutional in nature. Results of our trials for our other product candidates could reveal a high and unacceptable severity and frequency of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Further, any observed drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial, or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition and prospects.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the product s label;
- we may be required to create a medication guide for distribution to patients that outlines the risks of such side effects;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy and operational results.

As one of the central elements of our business strategy and clinical development approach, we seek to identify molecularly-defined subsets of patients within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In order to assist in identifying those subsets of patients, a companion diagnostic, which is a test or measurement that evaluates the presence of biomarkers in a patient could be used. We anticipate that the development of companion diagnostics concurrently with our product candidates will help us more accurately identify the patients who belong to the target subset, both during our clinical trials and in connection with the commercialization of our product candidates. We may need to rely on third party collaborators to successfully develop and commercialize companion diagnostics. To date, we have not developed relationships with any such third-party collaborators to develop companion diagnostics for any of our product candidates. We may not be able to

establish arrangements with any such third-party collaborators for the development and production of companion diagnostics when needed or on terms that are beneficial to us, or at all, which could negatively affect our development efforts with respect to our drug product candidates and materially harm our business, operations and prospects.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory clearance or approval prior to their commercialization. We may be dependent on the sustained cooperation and effort of any third-party collaborators with whom we

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may partner in the future to develop and obtain clearance or approval for these companion diagnostics. We and our potential future collaborators may encounter difficulties in developing and obtaining clearance or approval for these companion diagnostics, including issues relating to the selectivity and/or specificity of the diagnostic, analytical validation, reproducibility, or clinical validation. Any delay or failure by us or our potential future collaborators to develop or obtain regulatory clearance or approval of any companion diagnostics could delay or prevent approval of our related product candidates. In addition, our potential future collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and we or they may experience difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. In addition, the third parties with whom we may contract to develop and produce companion diagnostics could decide to discontinue selling or manufacturing the companion diagnostic, and we may not be able to enter into arrangements with other parties to obtain supplies of alternative diagnostic tests on a timely basis or reasonable terms, or at all. The occurrence of any such event could adversely affect and/or delay the development or commercialization of our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication that does not produce any commercially viable products and may fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our efforts on particular research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Further, our resource allocation decisions may result in our use of funds for research and development programs and product candidates for specific indications that may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such failure to improperly assess potential product candidates could result in missed opportunities and/or our focus on product candidates with low market potential, which would harm our business and financial condition.

We may not be able to obtain orphan drug exclusivity for the product candidates for which we seek it, which could limit the potential profitability of such product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it receives the designation, then the product is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the exclusivity period except in limited situations.

We expect that we may in the future pursue orphan drug designations for at least some of our product candidates. However, obtaining an orphan drug designation can be difficult and we may not be successful in doing so for any of our product candidates. Even if we were to obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same condition if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. The failure to obtain an orphan drug designation for any product candidates we may develop for the treatment of rare cancers, and/or the inability to

maintain that designation for the duration of the applicable

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exclusivity period, could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

If we seek and obtain a fast track or breakthrough therapy designation or accelerated approval by the FDA for any of our product candidates, such designations may not actually lead to a faster development or regulatory review or approval process or any other material benefits.

We may in the future seek fast track designation for some of our product candidates that reach the regulatory review process. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply to the FDA for a fast track designation for the product candidate. If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the remaining information. In addition, a fast track product may be eligible for accelerated approval, as described below. The FDA has broad discretion over whether to grant a fast track designation and, as a result, even our product candidates that may be eligible for such a designation may not receive it. Even if we were to receive fast track designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Additionally, the FDA could withdraw a fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Additionally, we may in the future seek a breakthrough therapy designation for some of our product candidates. The Food and Drug Administration Safety and Innovation Act established the new breakthrough therapy designation for drugs intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

As with fast track designation, designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and may determine not to grant such a designation. Even if we receive a breakthrough therapy designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Further, obtaining a breakthrough therapy designation does not assure or increase the likelihood of the FDA s approval of the applicable product candidate. In addition, even if one or more of our product candidates qualifies as a breakthrough therapy, the FDA could later determine that those products no longer meet the conditions for the designation or determine not to shorten the time period for FDA review or approval.

We may also in the future seek accelerated approval for some of our product candidates. Under the FDA s accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening disease or condition that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical endpoint, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or sooner than clinical

endpoints. As with fast track designation and breakthrough therapy designation, the FDA has broad discretion over whether to grant approval based on a surrogate endpoint.

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Accordingly, even if we believe one of our product candidates meets the criteria for accelerated approval, the FDA may disagree and may determine not to grant such approval.

In addition, a product candidate approved on such an accelerated basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or validate the surrogate endpoint or otherwise confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct preclinical and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely, and expect to continue to rely, upon third-party CROs to execute our preclinical and clinical trials and to monitor and manage data produced by and relating to those trials. However, we may not be able to establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug product candidates and materially harm our business, operations and prospects.

We currently have only limited control over the activities of the CRO we have engaged to continue the Phase I/II clinical trial for RXDX-101, and we expect the same to be true for any CROs we may engage in the future. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on any CRO does not relieve us of our regulatory responsibilities. Based on our present expectations, we, our CROs and our clinical trial sites are required to comply with good clinical practices, or GCPs, for all of our product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a product candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such product candidate. In addition, our clinical trials are required to be conducted with product produced in compliance with current good manufacturing practice requirements, or cGMPs. Our or our CROs failure to comply with those regulations may require us to repeat clinical trials, which would also require significant cash expenditures and delay the regulatory approval process.

Agreements governing relationships with CROs generally provide those CROs with certain rights to terminate a clinical trial under specified circumstances. If a CRO that we have engaged terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute CRO, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable trial would experience delays or may not be completed. In addition, our CROs are not our employees, and except for remedies available to us under any agreements we enter with them, we are unable to control whether or not they devote sufficient time and resources to our clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to a failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize, the affected product candidates. As a result, our

operations and the commercial prospects for the effected product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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We plan to rely completely on third parties to manufacture our preclinical and clinical drug supplies and any approved product candidates, and our operations could be harmed if those third parties fail to provide sufficient quantities of product in accordance with applicable regulatory and contractual obligations.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our preclinical studies and clinical trials or commercial quantities of any product candidates that may obtain regulatory approval. As a result, we expect that we will need to rely completely on third-party manufacturers for those services. We presently have only a limited supply of RXDX-101 and RXDX-102, which NMS agreed to provide to us in connection with our recent in-licensing of the rights to develop those product candidates. We have recently entered into a short term supply agreement with NMS to provide us with additional RXDX-101 clinical supply. We also are evaluating NMS and other third-party manufacturers for long-term supply of RXDX-101. We do not currently have any long-term supply commitments in place. We also do not currently have arrangements in place for redundant supply of bulk drug substance. We may not be able to establish these or any other supply relationship when needed, on reasonable terms, or at all. Any failure to secure sufficient supply of our product candidates for clinical testing or, in the future, commercial purposes would materially harm our operations and financial results.

We expect that the facilities to be used by any contract manufacturers we engage to manufacture our product candidates will be inspected by the FDA in connection with any NDA that we submit. We will not control the manufacturing process of, and will be dependent on, our contract manufacturing partners for compliance with cGMPs for the manufacture of clinical and, if regulatory approval is obtained, commercial quantities of our product candidates. In addition, we expect to have no control over the ability of our contract manufacturers to maintain adequate compliance with cGMPs. If any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our product candidates or commercializing our products, if approved, unless and until we could engage a substitute contract manufacturer that could comply with such requirements, which we may not be able to do. Any such failure by any of our contract manufacturers would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We expect to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. We do not have, nor do we expect to enter, any agreements for the commercial production of these raw materials, and we do not expect to have any control over the process or timing of our manufacturers acquisition of raw materials needed to produce our product candidates. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to a manufacturer s need to replace a third-party supplier of raw materials could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. Additionally, if our manufacturers or we are unable to purchase these raw materials to commercially produce any of our product candidates that gain regulatory approval, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Any Commercialization of Our Product Candidates

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and review. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed, or contain requirements for potentially costly

post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA s or EMA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own

sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, the products may not gain market acceptance among physicians, health care payors, patients and the medical community, which is critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product candidate, any associated companion diagnostic, and/or competitive products;
- the clinical indications for which the drug is approved;
- the approval, availability, market acceptance and reimbursement for any companion diagnostic;
- the ability of a companion diagnostic to successfully identify all tested patients that harbor the underlying molecular alteration that our product targets;
- acceptance of the drug as a safe and effective treatment by physicians, major operators of cancer clinics and patients;
- the size of the markets for the product candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the potential and perceived advantages of the product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with the product candidate;
- the safety of the product candidate as demonstrated through broad commercial use including, potentially, under conditions not tested in clinical trials;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales, marketing and distribution efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

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With respect to our lead product candidate, we are aware of one agent that has been approved by the FDA for ALK-positive NSCLC, which is Pfizer s Xalkori®/crizotinib, and we are aware of several other products in development targeting TrkA, TrkB, TrkC, ROS1 and/or ALK for the treatment of cancer, some of which may be in a more advanced stage of development than RXDX-101. There are also many other compounds directed to other molecular targets that are in clinical development by a variety of companies to treat cancer types that we may choose to pursue with RXDX-101.

Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in certain of our competitors. As a result, these companies may be able to obtain regulatory approval more rapidly than we can and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing drug products that are more effective or less costly to produce or purchase on the market than any product candidate we are currently developing or that we may seek to develop in the future. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of or in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval, or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business and ability to achieve profitability from future sales of our approved product candidates, if any.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell on a profitable basis any products for which we obtain marketing approvals.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Market acceptance and sales of any of our product candidates that obtain regulatory approval in domestic or international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates, and may be affected by existing and future healthcare reform measures.

Pricing and reimbursement for any of our approved product candidates is uncertain. Government authorities and other third-party payors decide which drugs they will pay for and establish reimbursement levels for them, and obtaining coverage and reimbursement approval for a product from any such third-party payor is a time consuming and costly process. Adoption of our product candidates by the medical community may be limited if doctors, patients and other key market participants do not receive adequate partial or full reimbursement for our approved products, if any. As a result, any denial of private or government payor coverage or inadequate reimbursement for use of our product candidates, if any are commercialized, could harm our business and reduce our prospects for generating revenue.

Further, there have been, and may continue to be, legislative and regulatory proposals at the federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and

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other payors of healthcare services to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our product candidates that are approved for marketing in that country.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our product candidates.

We could be subject to product liability lawsuits if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenues from product sales; and

the inability to commercialize our product candidates.

Our inability to retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the clinical testing and commercialization of products we develop. We have obtained product liability insurance covering clinical trial activity as a result of our assumption

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of control of the RXDX-101 clinical trials currently being conducted in Italy. We may wish to obtain additional such insurance covering studies or trials in other countries should we seek to expand those clinical trials or commence new clinical trials in other jurisdictions or increase the number of patients in any clinical trials we may pursue. We also may determine that additional types and amounts of coverage would be desirable at later stages of clinical development of our product candidates or upon commencing commercialization of any product candidate that obtains required approvals. However, we may not be able to obtain any such additional insurance coverage when needed on acceptable terms or at all. If we do not obtain or retain sufficient product liability insurance, we could be responsible for some or all of the financial costs associated with a product liability claim relating to our preclinical and clinical development activities, in the event that any such claim results in a court judgment or settlement in an amount or of a type that is not covered, in whole or in part, by any insurance policies we may have or that is in excess of the limits of our insurance coverage. We may not have, or be able to obtain, sufficient capital to pay any such amounts that may not be covered by our insurance policies.

Risks Related to Our Intellectual Property

If we breach any of the agreements under which we license from third parties the commercialization rights to our product candidates, we could lose license rights that are important to our business and our operations could be materially harmed.

We have in-licensed from NMS the use, development and commercialization rights for RXDX-101 and RXDX-102. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of that agreement and the rights we license under it. The license agreement provides that we are subject to diligence obligations relating to the commercialization and development of a product based on either or both of RXDX-101 or RXDX-102, milestone payments, royalty payments and other obligations. In addition to our license agreement with NMS, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential product candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of our license agreement with NMS, or any future license agreement we may enter on which our business or product candidates are dependent, NMS or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates, including, with respect to our license agreement with NMS, RXDX-101 and RXDX-102. The loss of the rights licensed to us under our license agreement with NMS, or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our trade secret or other confidential information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from this information.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may

not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the

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patents we hold or pursue is threatened, our ability to commercialize any product candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered product candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our product candidates.

The license agreement with NMS grants us an exclusive, worldwide license under a portfolio of patents and patent applications directed to the RXDX-101 and RXDX-102 composition of matter, which begin to expire in 2029 for the patents and applications relating to RXDX-101 and in 2028 for the patents and applications relating to RXDX-102. While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for either RXDX-101 or RXDX-102, the applicable patents may not meet the specified conditions for eligibility for any such term extension and, even if eligible, we may not be able to obtain any such term extension. Further, because filing, prosecuting and enforcing patents in multiple jurisdictions can be expensive, we may elect to pursue patent protection relating to our product candidates in only certain jurisdictions. As a result, competitors would be permitted to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, any of which could compete with our product candidates.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know-how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. 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 difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secret intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims that cover the use or manufacture of our product candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes one or more claims of these patents. If our activities or product candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such product candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or

unenforceable.

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Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and/or redesign our infringing product candidates or methods, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on commercially reasonable terms, or at all. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our product candidates and our business could materially suffer.

We may desire, or be forced, to seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify product candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those product candidates, as we have done with RXDX-101 and RXDX-102. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.

While we expect that we will generally seek to gain the right to fully prosecute any patents covering product candidates we may in-license from third-party owners, there may be instances when platform technology patents that cover our product candidates remain controlled by our licensors. For instance, NMS has retained certain patent prosecution rights under our license agreement relating to RXDX-101 and RXDX-102. If any of our current or future licensing partners that retain the right to prosecute patents covering the product candidates we license from them fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected product candidates may suffer.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming and distract management. If we pursue any litigation, a court may decide that a patent of ours or our licensor s is not valid or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in the applicable jurisdictions.

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Interference proceedings provoked by third parties or brought by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed.

We are seeking patent protection for some of our technology and product candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and product candidates, our business may be adversely impacted.

In addition, issued patents and pending international applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents unenforceable or by prematurely terminating pending international applications.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. 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, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Managing Any Growth We May Experience

We will need to grow the size of our organization, and we may experience difficulties in managing any growth we may achieve.

As of February 28, 2014, we had 17 employees, 15 of whom were full-time and two of whom were part-time. As our development and commercialization plans and strategies develop, we expect to need additional research, development, managerial, operational, sales, marketing, financial, accounting, legal and other resources. Future growth would impose significant added responsibilities on members of management, including:

effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals;

effectively managing our discovery research and preclinical development;

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identifying, recruiting, maintaining, motivating and integrating additional employees;

effectively managing our internal development efforts;

establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties;

developing and managing new divisions of our internal business, including any sales and marketing segment we elect to establish;

maintaining our compliance with public company reporting and other obligations, including establishing and maintaining effective internal control over financial reporting and disclosure controls and procedures; and

improving our managerial, development, operational and finance systems.

We may not be able to accomplish any of those tasks, and our failure to do so could prevent us from effectively managing future growth, if any, and successfully growing our company.

We may in the future be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply with any such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, anti-kickback and false claims statutes. These laws may impact, among other things, any sales, marketing and education programs we may develop in the future and the manner in which we implement any of those programs. In addition, we may be subject to federal and state patient privacy regulations, such as the federal Health Insurance Portability and Accountability Act of 1996. If our operations are found to be in violation of any of those laws or any other governmental regulations that may apply to us in connection with marketing and sales of any product candidates that may gain regulatory approval, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial condition.

If we fail to comply with environmental, health and safety laws and regulations that apply to us, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of any hazardous materials we use and wastes we produce. The use of these materials in our business could result in contamination or injury, which could cause damage for which we may be responsible but may not have sufficient resources to pay. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations, which we may not be able to afford.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide

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adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts or impact the research activities we pursue, particularly with respect to research involving human subjects or animal testing. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could cause our financial condition to suffer.

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

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. To the extent we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a cumulative change in equity ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period), the corporation s ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes to offset its post-ownership change income and taxes may be limited. We may have experienced an ownership change as a result of the October 31, 2013 merger in which Ignyta Operating became our wholly owned subsidiary and/or our November 2013 private placements of our common stock and may experience one or more ownership changes as a result of this offering or future transactions in our stock, and as a result we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately $7.3 million that could be limited if the merger or the private placements is an ownership change, or if we experience any other ownership change, which could potentially result in increased future tax liability to us.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity and other events beyond our control, the occurrence of which could materially harm our business.

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power, and any future blackouts could disrupt our operations. We are vulnerable to a major earthquake, wildfire and other natural disasters, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. We do not carry any business interruption insurance that would compensate us for actual losses from

interruption of our business that may occur, and any losses or damages incurred by us could cause our business to materially suffer.

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Risks Related to Ownership of our Common Stock and this Offering

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.

There is not now, nor has there been since our inception, any significant volume of trading activity in our common stock or an active market for shares of our common stock, and an active trading market for our shares may never develop or be sustained after this offering. As a result, investors in our common stock must bear the economic risk of holding those shares for an indefinite period of time. Although our common stock is quoted on the OTCQB Marketplace, or OTCQB, and OTC Bulletin Board, or OTCBB, over-the-counter quotation systems, trading of our common stock on such systems has only recently commenced and continues to be extremely limited and sporadic and at very low volumes. We currently expect that our common stock will be listed on the NASDAQ Capital Market after the pricing of this offering, but an active trading market for our common stock may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for you to sell the shares you purchase in this offering without depressing the market price for the shares or at all. Further, an unestablished trading market for our common stock may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control.

The quoted prices for our common stock currently are, and are likely to continue to be, highly volatile, and could be subject to wide fluctuations. That price fluctuation could be in response to various factors, some of which may be beyond our control. In addition to the factors discussed in this Risk Factors section and elsewhere in this prospectus, these factors include:

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;

changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;

disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;

our dependence on third parties, including CROs as well as our potential partners that produce companion diagnostic products;

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failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;

actual or anticipated variations in quarterly operating results, liquidity or other indicators of our financial condition;

failure to meet or exceed the estimates and projections of the investment community;

overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our ability to maintain an adequate rate of growth and manage such growth;

issuances of debt or equity securities;

sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;

trading volume of our common stock;

ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

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. 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, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

The public offering price of our common stock is 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 outstanding options or warrants are exercised, you will incur further dilution. Based on an assumed public offering price of $ per share, which is the last reported sale price for our common stock as reported on the OTCQB on , 2014, 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 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. For further information on this calculation, see Dilution elsewhere in this prospectus.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of February 28, 2014, a total of 13,534,876 shares of our common stock were outstanding. Of those shares, approximately 9,017,574 were freely tradable, without restriction, in the public market. Such shares represented 66.62% of our outstanding shares of common stock as of that date. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline. Additionally, the 4,516,469 outstanding shares of our common stock that we issued to former stockholders of Ignyta Operating in connection with the closing of the merger in which Ignyta Operating became our wholly owned subsidiary will become freely tradable upon the expiration of certain lock-up restrictions applicable to those shares, which prohibit their sale, disposition or other transfer for a period of 180 days following the closing of our November 6, 2013 private placement, and the lapse of securities law restrictions on their resale, which could occur under Rule 144 after the end of the 12-month period following November 1, 2013, the date on which we initially filed with the SEC our Current Report on Form 8-K containing Form 10 information.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act, and any future registration of such shares under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The resale of shares covered by our effective resale registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional equity capital. We filed a registration statement with the SEC, which was declared effective on February 11, 2014, to register the resale of 9,010,238 shares of our common stock, which represents all of the shares of our common stock issued and sold in our private placements consummated in November 2013. The resale registration statement permits the resale of these shares at any time without restriction. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, because there are a large number of shares registered pursuant to the resale registration statement,

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the selling stockholders named in such registration statement may continue to offer shares covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the resale registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We may have material liabilities that were not discovered before, and have not been discovered since, the closing of our October 2013 merger.

As a result of the October 31, 2013 merger in which Ignyta Operating became our wholly owned subsidiary, the former business plan and management of Ignyta, previously known as Infinity Oil & Gas Company, have been abandoned and replaced with the business and management team of Ignyta Operating. Prior to the merger, there were no relationships or other connections among the businesses or individuals associated with those two entities. As a result, Ignyta may have material liabilities based on activities before the merger that have not been discovered or asserted. We could experience losses as a result of any such undisclosed liabilities that are discovered in the future, which could materially harm our business and financial condition. Although the merger agreement entered into in connection with the merger contains customary representations and warranties from Ignyta concerning its assets, liabilities, financial condition and affairs, there may be limited or no recourse against Ignyta s pre-merger stockholders or principals in the event those representations prove to be untrue. As a result, our current and future stockholders will bear some, or all, of the risks relating to any such unknown or undisclosed liabilities.

We may be exposed to additional risks as a result of going public by means of a reverse merger transaction.

We may be exposed to additional risks because the business of Ignyta Operating has become a public company through a reverse merger transaction. There has been increased focus in recent years by government agencies on transactions such as the merger in which Ignyta Operating became our wholly owned subsidiary, and we may be subject to increased scrutiny by the SEC and other government agencies and holders of our securities as a result of the completion of that transaction. Further, as a result of our existence as a shell company under applicable rules of the SEC prior to the closing of the merger on October 31, 2013, we are subject to certain restrictions and limitations for certain specified periods of time relating to potential future issuances of our securities and compliance with applicable SEC rules and regulations. Additionally, our going public by means of a reverse merger transaction may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms following the merger because there may be little incentive to those brokerage firms to recommend the purchase of our common stock. The occurrence of any such event could cause our business or stock price to suffer.

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We will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

We currently expect that our common stock will be listed on the NASDAQ Capital Market after the pricing of this offering. As a public company listed on the NASDAQ Capital Market, and particularly if and after we cease to be an emerging growth company or a smaller reporting company, we will incur significant legal, accounting and other expenses that Ignyta Operating did not incur as a private company and that we did not incur prior to the listing of our common stock on the NASDAQ Capital Market. In addition, the rules and regulations of the SEC and the NASDAQ Capital Market impose numerous requirements on public companies, including requirements relating to our corporate governance practices, with which we will need to comply. Further, since we are subject to the Exchange Act, we are required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive.

Ignyta Operating was not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the October 31, 2013 merger in which Ignyta Operating became our wholly owned subsidiary. Our management team and Board of Directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff and engaging consultants to assist in designing and implementing such procedures. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors views of us.

We are required to comply with certain aspects of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act requires public companies to, among other things, conduct an annual review and evaluation of their internal controls. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We are an emerging growth company and a smaller reporting company, which allows us to take advantage of certain reduced disclosure obligations as a public reporting company that may make our common stock less attractive to investors. Additionally, as an emerging growth company, we have elected to delay the adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

We are an emerging growth company under the JOBS Act. We are also a smaller reporting company as defined in applicable rules under the Exchange Act. As an emerging growth company and a smaller reporting company, we are

eligible to take advantage of certain extended accounting standards and exemptions from

various reporting requirements that are not available to public reporting companies that do not qualify for those classifications. For instance, we are exempt from 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 financial statements, commonly known as an auditor discussion and analysis; we are not required to hold a nonbinding advisory stockholder vote on executive compensation or any golden parachute payments not previously approved by stockholders; we are not required to comply with the requirement of auditor attestation of management s assessment of internal control over financial reporting, which is required for some other public reporting companies by Section 404 of the Sarbanes-Oxley Act of 2002; we are eligible for reduced disclosure obligations regarding executive compensation in our periodic and annual reports; and we are eligible for reduced financial statement disclosure in any registration statements under the Securities Act or reports under the Exchange Act that we may file. For as long as we continue to be an emerging growth company and/or a smaller reporting company, which we anticipate will be for the foreseeable future, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. As a result, our publicly available disclosure may not be as robust or comprehensive as that of other public reporting companies that do not qualify for those classifications.

Further, as an emerging growth company, we can elect to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to take advantage of this extended transition period. Since we will not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our financial statements may not be comparable to the financial statements of other public companies that comply with the effective dates of those accounting standards.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As of February 28, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 32% of our outstanding voting stock (which includes shares they had the right to acquire within 60 days). Accordingly, our directors and executive officers and large stockholders have significant influence over our affairs due to their substantial ownership coupled with the positions of some of these stockholders on our management team, and have substantial voting power to approve matters requiring the approval of our stockholders. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership in our Board of Directors and management team and certain other large stockholders may prevent or discourage unsolicited acquisition proposals or offers for our common stock that some of our stockholders may believe is in their best interest.

If we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 100,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the rights, preferences and privileges that our Board of Directors may determine from time to time. Upon the closing of our private placements of our common stock on November 6, 2013 and November 29, 2013, we issued an aggregate of 9,010,238 shares of our common stock, which was equal to approximately 66.62% of our issued and outstanding capital stock as of February 28, 2014. In addition to capital raising activities such as public and private placements of our common stock, which we expect to continue to pursue in order to raise the funding we will need in order to continue our operations, other possible business and financial uses for our authorized capital stock include, without limitation, future stock splits, acquiring

other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances,

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attracting and retaining employees by the issuance of additional securities under our equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the best interest of our company. Additionally, shares of our capital stock could be used for anti-takeover purposes or to delay or prevent changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may not enhance stockholder value, they may have rights, preferences and privileges that are superior to those of our common stock, and they may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution to the percentage ownership of our stockholders and could cause our stock price to fall.

Even after giving effect to the funds raised in this offering, we expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Pursuant to our Amended and Restated 2011 Stock Incentive Plan, or the Ignyta Plan, we are authorized to grant equity awards to our employees, directors and consultants for up to an aggregate of 2,712,652 shares of our common stock. Additionally, as of February 28, 2014, there were outstanding options granted under the Ignyta Plan that are exercisable for up to 1,627,153 shares of our common stock, and there were outstanding warrants to acquire up to 41,668 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Nevada law may discourage an acquisition of us by others, even if the acquisition may be beneficial to some of our stockholders.

Provisions in our Amended and Restated Articles of Incorporation and Bylaws, as well as certain provisions of Nevada law, could make it more difficult for a third-party to acquire us, even if doing so may benefit some of our stockholders. These provisions include the authorization of 10,000,000 shares of blank check preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval.

Because we are incorporated in Nevada, we may in the future be governed by Nevada s statutes governing combinations with interested stockholders and control share acquisitions, which may discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by or beneficial to our stockholders. However, we are not at this time subject to Nevada s laws governing combinations with interested stockholders because we have elected to opt out of such laws in our Amended and Restated Articles of Incorporation, and we believe that we are not at this time subject to Nevada s control share acquisition laws because they apply only to Nevada corporations with at least 100 Nevada residents as stockholders of record.

Any provision of our Amended and Restated Articles of Incorporation or Bylaws or of Nevada law that is currently or in the future applicable to us and has the effect of delaying or deterring a change in control could

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limit the opportunity for our stockholders to receive a premium for their shares of our common stock in the event that a potentially beneficial acquisition is discouraged, and could also affect the price that some investors are willing to pay for our common stock.

The elimination of personal liability against our directors and officers under Nevada law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Amended and Restated Articles of Incorporation and our Bylaws eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Nevada law. Further, our Amended and Restated Articles of Incorporation and our Bylaws and individual indemnification agreements we have entered with each of our directors and executive officers provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by the Nevada law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

Other than a $3.50 per share cash dividend we declared and paid in connection with and prior to the closing of the October 31, 2013 merger in which Ignyta Operating became our wholly owned subsidiary, we have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our loan agreement with SVB. Any future payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of the our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this prospectus that are not descriptions of historical facts, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated products, are forward-looking statements that are based on management s current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition and stock price could be materially negatively affected. In some cases, you can identify forward-looking statements by terminology including anticipates, believes, can, continue, could, estimates, expects, intends, may, plans, potential, would or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include those set forth in the section titled Risk Factors including, without limitation, risks relating to:

- the results of our research and development activities, including uncertainties relating to the discovery of potential product candidates and the preclinical and clinical testing of our product candidates;
- the early stage of our product candidates presently under development;
- our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates, and any of our other future product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our need for substantial additional funds in order to pursue our business plan and the uncertainty of whether we will be able to obtain the funding we need;
- our ability to retain or hire key scientific or management personnel;
- our ability, with partners, to validate, develop and obtain regulatory approval of companion diagnostics for our product candidates;
- our ability to protect our intellectual property rights, including patent and other intellectual property rights;
- our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators;
- our ability to develop successful sales and marketing capabilities in the future as needed;

- the size and growth of the potential markets for any of our product candidates, and the rate and degree of market acceptance of any of our product candidates;
- competition in our industry;
- the impact of healthcare reform legislation; and
- regulatory developments in the United States and foreign countries.

We operate in a very competitive and rapidly-changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to

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differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. The forward-looking statements included in this prospectus speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purpose of this offering is to obtain additional capital to support our operations. We intend to use the net proceeds of this offering to fund the development of our lead product candidate, RXDX-101, and for other research and development of our other product candidates, including building Ignyta s central diagnostic laboratory and investing in our Oncolome database, working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses or products or to obtain rights to such complementary technologies. We have no commitments with respect to any such acquisitions or investments.

We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. The amount and timing of our actual expenditures will depend upon numerous factors, including the status of our clinical trials relating to RXDX-101, and other factors described under Risk Factors in this prospectus, as well as the amount of cash used in our operations. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the use 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 stock. Pending their use, we plan to invest the net proceeds from this offering in money market funds short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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PRICE RANGE OF OUR COMMON STOCK

Our common stock is quoted on the OTCQB and OTCBB over-the-counter quotation systems under the ticker symbol RXDX. On , 2014, the last reported sale price for our common stock as reported on the OTCQB was $ per share. There was no trading of our common stock on the OTCQB, OTCBB or any other market, exchange or quotation system before December 2013. Although our common stock is quoted on the OTCQB and OTCBB, there is a limited trading market for our common stock and there have been few trades in our common stock to date. Because our common stock is thinly traded, any reported sale prices may not be a true market-based valuation of our common stock.

The table below sets forth reported high and low closing sale prices for our common stock for the fiscal quarters indicated as reported on the OTCQB.

	High	Low
Fiscal Year Ended December 31, 2012		
Quarter ended March 31, 2012*		
Quarter ended June 30, 2012*		
Quarter ended September 30, 2012*		
Quarter ended December 31, 2012*		
Fiscal Year Ended December 31, 2013		
Quarter ended March 31, 2013*		
Quarter ended June 30, 2013*		
Quarter ended September 30, 2013*		
Quarter ended December 31, 2013	$ 7.00	$ 0.01
Fiscal Year Ending December 31, 2014		
Quarter ending March 31, 2014 (through , 2014)	$	$

* There was no market for our common stock during this period.

Holders

As of , 2014, there were holders of record of our common stock.

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DIVIDEND POLICY

In connection with and prior to the closing of the merger in which Ignyta Operating became our wholly owned subsidiary, on October 31, 2013, we declared a $3.50 per share cash dividend to our common stockholders of record as of that date and time. Other than the dividend declared in connection with the merger, we have never declared nor paid any cash dividends to stockholders. We do not intend to pay cash dividends on our common stock for the foreseeable future, and currently intend to retain any future earnings to fund our operations and the development and growth of our business. The declaration of any future cash dividend, if any, would be at the discretion of our Board of Directors and would depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions. In addition, our ability to pay cash dividends is currently prohibited by the terms of our loan agreement with SVB.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents as well as capitalization as of December 31, 2013:

on an actual basis; and

on a pro forma basis to give effect to the sale by us of $40,000,000 of shares of common stock in this offering at the assumed public offering price of $ per share (the last reported sale price for our common stock as reported on the OTCQB on , 2014), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	As of December 31, 2013	
	Actual	Pro Forma(1) (unaudited)
Cash and cash equivalents	$ 51,803,716	
Preferred stock, $.00001 par value; 10,000,000 shares authorized, no shares issued and outstanding		
Common stock, $.00001 par value; 100,000,000 shares authorized, 13,934,876 shares issued and outstanding, actual; 100,000,000 shares authorized, shares issued and outstanding, pro forma	139	
Additional paid-in capital	57,360,406	
Deficit accumulated during the development stage	(15,572,940)	
Total stockholders equity	41,787,605	
Total capitalization	$ 41,787,605	

(1) A 5% increase or decrease in the assumed public offering price of $ per share, the last reported sale price for our common stock as reported on the OTCQB on , 2014, would increase or decrease the number of shares of our common stock issued in this offering by approximately 5%.

The number of shares of common stock to be outstanding after this offering is based on 13,934,876 shares of common stock outstanding as of December 31, 2013, which does not include:

1,133,153 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2013, at a weighted average exercise price of $4.33 per share;

41,668 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2013, at a weighted average exercise price of $4.20 per share;

1,567,209 shares of common stock reserved for future issuance under the Ignyta Plan as of December 31, 2013; or

the exercise by us of a contractual right to repurchase 400,000 shares of restricted common stock in February 2014 in connection with the departure of an employee.

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DILUTION

Investors purchasing shares of our common stock in this offering will experience immediate and substantial dilution in the as adjusted net tangible book value of their shares of common stock. Dilution in as adjusted net tangible book value represents the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock immediately after the offering.

The historical net tangible book value of our common stock as of December 31, 2013 was $41,787,605, or $3.00 per share. Historical net tangible book value per share of our common stock represents our total tangible assets (total assets less intangible assets) less total liabilities divided by the number of shares of common stock outstanding as of that date.

After giving effect to (i) the issuance of shares of common stock in this offering, at an assumed public offering price of $ per share (the last reported sale price for our common stock as reported on the OTCQB on , 2014), and (ii) the receipt of the estimated net proceeds of from the sale of of common stock in this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, net tangible book value as of December 31, 2013 would have been approximately $ million, or $ per share of common stock. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate dilution of $ per share to new investors purchasing our common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed public offering price per share		$
Historical net tangible book value per share as of December 31, 2013	$ 3.00	
Increase in net tangible book value per share attributable to new investors purchasing shares in this offering		
As adjusted net tangible book value per share after giving effect to this offering		
Dilution per share to new investors participating in this offering		$

If the underwriters exercise their option in full to purchase an additional $6,000,000 of shares of common stock in this offering, the as adjusted net tangible book value per share after the offering would be $ per share, the increase in the net tangible book value per share to existing stockholders would be $ per share and the dilution to new investors purchasing our common stock in this offering would be $ per share.

The above discussion and table are based on 13,934,876 shares of common stock outstanding as of December 31, 2013, which does not include:

- 1,133,153 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2013, at a weighted average exercise price of $4.33 per share;

41,668 shares of common stock issuable upon the exercise of outstanding warrants as of December 31, 2013, at a weighted average exercise price of $4.20 per share;

1,567,209 shares of common stock reserved for future issuance under the Ignyta Plan as of December 31, 2013; or

the exercise by us of a contractual right to repurchase 400,000 shares of restricted common stock in February 2014 in connection with the departure of an employee.

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To the extent that outstanding exercisable options or warrants are exercised, you may experience further dilution. If all outstanding exercisable options and warrants with exercise prices below $ per share (the last reported sale price for our common stock as reported on the OTCQB on , 2014) were exercised, our as adjusted net tangible book value as of December 31, 2013 (calculated on the basis of the assumptions set forth above) would have been approximately $ million, or approximately $ per share, causing immediate dilution of $ per share to new investors purchasing shares in this offering.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data for the periods presented and should be read together with the sections of this prospectus entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as our consolidated financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statement of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results we expect in the future.

	Year Ended December 31,	
	2013	2012
	(audited)	
Consolidated Statements of Operations Data:		
Revenue	$	$
Expenses		
Research and development	10,170,866	708,043
General and administrative	3,730,941	547,882
Loss from operations	(13,901,807)	(1,255,925)
Other expense	(309,741)	(22,619)
Loss before income taxes	(14,211,548)	(1,278,544)
Income tax provision	2,095	1,308
Net loss	$ (14,213,643)	$ (1,279,852)
Basic and diluted loss per share of common stock	$ (3.83)	$ (2.00)
Weighted average number shares outstanding	3,711,885	640,364

	As of December 31, 2013
	(audited)
Consolidated Balance Sheet Data:	
Cash and cash equivalents	$ 51,803,716
Total assets	53,318,840
Total liabilities	11,531,235
Deficit accumulated during the development stage	(15,572,940)
Total stockholders equity	41,787,605

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MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with Selected Consolidated Financial Data and our consolidated financial statements and related notes appearing 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, includes forward-looking statements that involve risks and uncertainties as described under the heading Special Note Regarding Forward-Looking Statements elsewhere in this prospectus. You should review the disclosure under the heading Risk Factors in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

On October 31, 2013, Ignyta Operating, Inc., a private Delaware corporation previously named Ignyta, Inc., or Ignyta Operating, merged with and into IGAS Acquisition Corp., a wholly owned subsidiary of Ignyta, Inc., a Nevada corporation previously named Infinity Oil & Gas Company, or Ignyta, formerly a shell company under applicable rules of the Securities and Exchange Commission. Ignyta Operating survived the merger as a wholly owned subsidiary of Ignyta. In the merger, Ignyta acquired the business of Ignyta Operating and continued the business operations of Ignyta Operating. The merger is accounted for as a reverse merger and recapitalization, with Ignyta Operating as the acquirer and Ignyta as the acquired company for financial reporting purposes. As a result, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the merger are those of Ignyta Operating and are recorded at the historical cost basis of Ignyta Operating, and the consolidated financial statements after completion of the merger will include the assets and liabilities of Ignyta and Ignyta Operating, the historical operations of Ignyta Operating and the operations of the combined enterprise of Ignyta and Ignyta Operating from and after the closing date of the merger. As a result of the accounting treatment of the merger and the change in Ignyta s business and operations from a shell company to a precision medicine biotechnology company, a discussion of the past financial results of the shell company is not pertinent or material, and the following discussion and analysis of our financial condition and results of operations are based on Ignyta Operating s financial statements.

Unless the context indicates or otherwise requires, the terms we, us, our and our company refer to (i) Ignyta Operating for discussions relating to periods before and through the closing of the merger, and (ii) Ignyta and its consolidated subsidiary, Ignyta Operating, for discussions relating to periods after the closing of the merger.

Overview

We were incorporated under the laws of the State of Delaware on August 29, 2011 with the name NexDx, Inc. We changed our name to Ignyta, Inc. on October 8, 2012. On October 31, 2013, a wholly owned subsidiary of Ignyta merged with and into our company, pursuant to which we became the wholly owned subsidiary of Ignyta. We changed our name to Ignyta Operating, Inc. in connection with the closing of the merger. On October 31, 2013, prior to the closing of the merger, (i) all then-outstanding shares of each series of our preferred stock were voluntarily converted by the holders thereof into shares of our common stock in accordance with our certificate of incorporation, and (ii) we effected a three-to-one reverse stock split of our issued and outstanding shares of capital stock. All share information in this discussion and analysis relating to our capital stock gives retroactive effect to that reverse stock split. On May 20, 2013, we completed our acquisition of Actagene Oncology, Inc., or Actagene, which merged with and into our company on that date.

We are a precision medicine biotechnology company dedicated to discovering or acquiring, then developing and commercializing, precisely targeted new drugs for cancer patients whose tumors harbor specific molecular alterations. We are pursuing an integrated drug and diagnostic, or Rx/Dx, strategy, where we anticipate pairing

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each of our product candidates with biomarker-based companion diagnostics, developed by us or by third parties with which we may partner, that are designed to identify the patients that are most likely to benefit from the use of the drugs we may develop. Our current development plans focus on two product candidates: RXDX-101, a tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in a Phase I/II clinical study in molecularly defined patient populations for the treatment of solid tumors; and RXDX-102, a tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors. As a result of the preliminary Phase I results relating to RXDX-101 that we have seen to date, we have decided to designate RXDX-102 as a back-up compound to RXDX-101. Accordingly, we will not devote further development resources to RXDX-102 unless the development program for RXDX-101 is unsuccessful. We have entered into a license agreement with NMS granting us exclusive global development and marketing rights to RXDX-101 and RXDX-102, which became effective on November 6, 2013. We also have three discovery stage programs, Spark-1, Spark-2 and Spark-3, directed to emerging oncology targets identified through mining of our database of information from proprietary and publicly available tumor samples, called Oncolome . Our strategy is to leverage the biomarker insights that we gain through our genetic and epigenetic mining of our Oncolome database and the knowledge of cancer biology of our management and drug discovery team, with the goal of discovering or acquiring, validating, developing and commercializing a pipeline of novel product candidates for the treatment of cancer.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, assembling our core capabilities in genetic and epigenetic based biomarker and drug target discovery, identifying potential product candidates and developing such candidates. Our product candidate development operations include preparing, managing and conducting preclinical and clinical studies and trials, preparing regulatory submissions relating to those product candidates and establishing and managing relationships with third parties in connection with all of those activities. We expect that in the future our operations may also, if regulatory approval is obtained, include pursuing the commercialization of our product candidates. To date, we have financed our operations primarily through funding received from private placement offerings of our capital stock and under a loan agreement. We have had no revenue to date. Since our inception and through December 31, 2013, we have raised an aggregate of approximately $70 million to fund our operations, of which approximately $60 million has been received from our issuance and sale of our equity securities and $10.0 million has been received under our loan and security agreement with SVB.

Since inception, we have incurred significant operating losses. Our net losses were $14.2 million, $1.3 million and $15.6 million for the periods ended December 31, 2013 and 2012 and for the period from August 29, 2011 (inception) through December 31, 2013, respectively. As of December 31, 2013, we had an accumulated deficit of $15.6 million. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and from year to year. We anticipate that our expenses will increase significantly now that we have assumed financial responsibility for the ongoing and any future studies and trials of RXDX-101 and as we: plan for the commencement of potential Phase II clinical development activities for RXDX-101; pursue the initial stages of development of our Spark-1, Spark-2 and Spark-3 programs; continue to discover, validate and develop additional novel product candidates; expand and protect our intellectual property portfolio; and hire additional scientific, business, accounting and financial personnel. In addition, we expect to incur additional costs associated with operating as a public company.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales or otherwise, and do not expect to generate any revenue from the sale of products in the near future.

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In the future, we expect that we will seek to generate revenue primarily from product sales, but may also seek to generate revenue from research funding, milestone payments and royalties on future product sales in connection with any out-license or other strategic relationships we may establish.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug and biomarker discovery efforts and the development of our product candidates, which include:

- license fees;