Ignyta, Inc.
Form S-1/A
February 07, 2014
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As filed with the Securities and Exchange Commission on February 7, 2014

No. 333-192956

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

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.

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)

With copies to:

Steven G. Rowles, Esq.

John A. de Groot, Esq.

Morrison & Foerster LLP

12531 High Bluff Drive, Suite 100

San Diego, California 92130

(858) 720-5100

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. x

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

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

SUBJECT TO COMPLETION, DATED FEBRUARY 7, 2014

PROSPECTUS

IGNYTA, INC.

9,010,238 Shares of Common Stock

This prospectus relates to the offering and resale by the selling stockholders identified herein of up to 9,010,238 shares of common stock, par value $0.00001 per share, of Ignyta, Inc. These shares include 7,740,142 shares of common stock issued and sold to accredited investors in a private placement offering closed on November 6, 2013 (the Initial Private Placement), and 1,270,096 shares of common stock issued and sold to accredited investors in a private placement offering closed on November 29, 2013 (the Subsequent Private Placement and, together with the Initial Private Placement, the Private Placements). All shares of common stock issued in the Private Placements were sold at a purchase price of $6.00 per share.

The selling stockholders may sell the shares of common stock on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market, in one or more transactions otherwise than on these exchanges or systems, such as privately negotiated transactions, or using a combination of these methods, and at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See the disclosure under the heading Plan of Distribution elsewhere in this prospectus for more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock hereunder.

The selling stockholders may sell any, all or none of the securities offered by this prospectus, and we do not know when or in what amount the selling stockholders may sell their shares of common stock hereunder following the effective date of this registration statement.

We will not receive any proceeds from the sale of our common stock by the selling stockholders in the offering described in this prospectus.

Our common stock is quoted for trading on the OTCQB Marketplace (OTCQB) and the OTC Bulletin Board (OTCBB) under the symbol RXDX . As of February 6, 2014, the closing bid price for our common stock as reported on the OTCQB was $10.10 per share.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under Risk Factors beginning on page 6 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment hereto. We have not authorized anyone to provide you with different information.

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.

This prospectus is dated , 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, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. 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, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. 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, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the 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, any applicable prospectus supplement or any related free writing 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.

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, has become our wholly owned subsidiary.

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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®, and Trailblaze®, and have pending trademark applications for Oncolome and Actagene . All other trademarks, trade names and service marks included in this prospectus are the property of their respective owners.

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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 read the entire prospectus carefully, including the risks related to our business and purchasing our common stock discussed under Risk Factors beginning on page 6 of this prospectus, and our financial statements and the accompanying notes beginning on page F-1 of this prospectus.

Our Company

Our Business

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 pursue an integrated drug and diagnostic, or Rx/Dx, strategy, where we anticipate pairing each of our drug 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 in-licensed 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, which is currently in preclinical development for the treatment of multiple cancers. We have entered into a license agreement with Nerviano Medical Sciences S.r.l. (NMS), an Italian state-owned biopharmaceutical company based in Nerviano, Italy, granting us exclusive global development and marketing rights to RXDX-101 and RXDX-102, which license agreement became effective on November 6, 2013. We are also pursuing three discovery stage programs, Spark-1, Spark-2, and Spark-3, directed to emerging oncology targets identified through mining 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 phenomena 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 utilize genetic and epigenetic analysis to discover and understand genes and gene pathways that are inappropriately activated in tumors, 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 drug candidates seek to address. Our strategy is to leverage the biomarker insights that we gain through our genetic and epigenetic mining of Oncolome and our management and drug discovery team s knowledge of cancer biology and capabilities in performing unique scientific testing techniques, with the goal of discovering or acquiring, validating, developing and commercializing a pipeline of novel drug 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, 2012 and for the three and nine months ended September 30, 2013 of $1.3 million, $1.2 million and $3.4 million, respectively, and we had an accumulated deficit as of September 30, 2013 of approximately $4.8 million. To date, we have financed our operations primarily through funding received from private placement offerings of our capital stock, such as the Private Placements, and under a loan agreement.

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. For a description of certain risks related to our business, see the disclosure under the heading Risk Factors beginning on page 6 of this prospectus.

The Private Placements

On November 1, 2013, we entered into a securities purchase agreement with 52 accredited investors providing for the issuance and sale to such investors of an aggregate of 7,740,142 shares of our common stock in the Initial Private Placement. The Initial Private Placement closed on November 6, 2013. The shares issued in the Initial Private Placement were sold at a purchase price per share of $6.00, for aggregate gross proceeds to us of approximately $46.4 million and aggregate net proceeds to us, after deducting for placement agent fees and expenses, of approximately $44.2 million. Ladenburg Thalmann & Co. Inc. served as the placement agent in the Initial Private Placement.

On November 27, 2013, we entered into a securities purchase agreement with 195 accredited investors providing for the issuance and sale to such investors of an aggregate of 1,270,096 shares of our common stock in the Subsequent Private Placement. The Subsequent Private Placement closed on November 29, 2013. The shares issued in the Subsequent Private Placement were sold at a purchase price per share of $6.00, for aggregate gross proceeds to us of approximately $7.6 million and aggregate net proceeds to us, after deducting for placement agent and other offering fees and expenses, of approximately $6.8 million. National Securities Corporation served as the placement agent in the Subsequent Private Placement.

Our aggregate gross proceeds from the Private Placements were approximately $54.1 million, and our aggregate net proceeds from the Private Placements, after deducting for placement agent, legal, registration and other offering related fees and expenses, were approximately $51.0 million.

The terms of the securities purchase agreements entered into with the investors in the Initial Private Placement and the Subsequent Private Placement (each, a Securities Purchase Agreement) contain substantially similar terms and provisions, including customary representations and warranties made by us to each of the investors and by each of the investors to us; *provided, however,* that the Securities Purchase Agreement we entered into in connection with the Initial Private Placement contains certain anti-dilution provisions that are not contained in the Securities Purchase Agreement we entered into in connection with the Subsequent Private Placement. Those anti-dilution provisions provide that, if we issue and sell certain of our equity securities at a purchase price per share lower than $6.00 within the 180-day period following November 6, 2013, the investors in the Initial Private Placement shall be entitled to receive such number of additional shares of our common stock as they would have received had such lower purchase price per share been applicable in the Initial Private Placement. Certain issuances of our equity securities are not subject to those anti-dilution provisions, including: issuances pursuant to the exercise or conversion of outstanding options, warrants or other convertible securities; issuances in connection with acquisitions, asset purchases, licenses, collaborations or strategic transactions that are not for the primary purpose of raising capital; issuances to our employees, officers, directors, consultants or advisors under stock incentive plans or other arrangements that are

approved by our Board of Directors; and issuances that the

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holders of a majority of the outstanding shares issued in the Initial Private Placement elect in writing to exclude from the application of such provisions. Both of the Securities Purchase Agreements we entered into in connection with the Initial Private Placement and the Subsequent Private Placement contain provisions that will obligate us to make certain payments to the investors thereunder if we or our transfer agent fail to timely remove certain restrictive legends from certificates representing the shares of common stock being offered hereby following the eligibility of such shares for resale under this registration statement or Rule 144 promulgated under the Securities Act of 1933, as amended (the Securities Act).

On November 6, 2013, we entered into a registration rights agreement (the Registration Rights Agreement) with the investors that participated in the Initial Private Placement. Upon the closing of the Subsequent Private Placement on November 29, 2013, the investors that participated in that financing became parties to and bound by, and the shares of our common stock purchased by them became subject to, the Registration Rights Agreement.

Pursuant to the terms of the Registration Rights Agreement, we agreed to file with the Securities and Exchange Commission (the SEC), within 45 days following November 6, 2013, the registration statement of which this prospectus forms a part, to register for resale all of the 9,010,238 shares of our common stock issued in the Private Placements. As a result of our initial filing of this registration statement, we are in compliance with that filing deadline. We have also agreed to use commercially reasonable efforts to have the registration statement declared effective within 150 days following November 6, 2013, or by April 7, 2014. If the registration statement is not declared effective on or before the applicable effectiveness deadline, we will be obligated pay to each selling stockholder an amount in cash equal to 1.0% of such stockholder s investment in the Private Placements on every monthly anniversary of such failure, until it is cured or all of such selling stockholder s securities to be registered hereunder have been or may be sold without restriction pursuant to Rule 144. The maximum aggregate amount of payments to be made by us as a result of such failures, whether by reason of a filing deadline failure, effectiveness deadline failure or any combination thereof, shall be an amount equal to 6.0% of each selling stockholder s investment in the Private Placements. Notwithstanding the foregoing, we will not be obligated to make any such payments with respect to any of the securities to be registered hereunder that we are unable to register due to limits imposed by the SEC s interpretation of Rule 415 promulgated under the Securities Act.

Under the Registration Rights Agreement, subject to exception in certain circumstances, we have agreed to keep this registration statement effective until the later of November 6, 2014 and such time as all of the securities to be registered hereunder have been sold under this registration statement or pursuant to Rule 144 or may be sold without restriction pursuant to Rule 144. If there is not an effective registration statement covering the resale of the securities to be registered hereunder at any time during the period required by the Registration Rights Agreement, then the selling stockholders will have piggyback registration rights with respect to any such securities that are not eligible for resale pursuant to Rule 144 in connection with any other registration statement we determine to file that would permit the inclusion of those shares.

The foregoing descriptions of the Securities Purchase Agreements and the Registration Rights Agreement do not purport to be complete, and are qualified in their entirety by the complete text of those agreements, which are attached as exhibits to this prospectus and are incorporated herein by reference.

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 (the Merger), and Ignyta

Operating survived the Merger and became our wholly owned subsidiary. Upon the closing

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of the Merger, we ceased to be a shell company under applicable rules of the SEC. In connection with the closing of the Merger, Ignyta changed its name to Ignyta, Inc. and Ignyta Operating changes 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.

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The Offering

This prospectus relates to the resale from time to time by the selling stockholders identified herein of up to 9,010,238 shares of our common stock. All of the common stock to be registered for resale hereunder was purchased by the selling stockholders in the Private Placements. We are not offering any shares for sale under the registration statement of which this prospectus is a part.

Common stock outstanding prior to this offering:	13,534,876 (1)
Common stock offered by the selling stockholders hereunder:	9,010,238 (2)
Common stock to be outstanding after this offering:	13,534,876 (1) (3)
Use of Proceeds:	We will not receive any proceeds from the sale of our common stock offered by the selling stockholders under this prospectus.
Risk Factors:	Investing in our securities involves a high degree of risk and purchasers may lose their entire investment. See the disclosure under the heading Risk Factors beginning on page 6 of this prospectus.
OTCBB Symbol:	RXDX

(1) As of February 6, 2014. Includes the 9,010,238 shares of our common stock issued and sold to the selling stockholders in the Private Placements and offered for resale by those selling stockholders under the registration statement of which this prospectus is a part.

(2) Includes (a) 7,740,142 shares of our common stock issued and sold in the Initial Private Placement, and (b) 1,270,096 shares of our common stock issued and sold in the Subsequent Private Placement.

(3) Excludes (a) 2,700,362 shares of our common stock that are reserved for future issuance under the Ignyta, Inc. Amended and Restated 2011 Stock Incentive Plan (the Ignyta Plan), which number does not include 12,290 outstanding shares of our common stock that have been issued upon the exercise of certain option awards granted under the Ignyta Plan, and (b) 41,668 shares of our common stock issuable upon the exercise of outstanding warrants with exercise prices ranging from $3.00 to $6.00 per share, none of which are being registered pursuant to the registration statement of which this prospectus is a part. As of February 6, 2014, there were outstanding options to purchase 1,113,153 shares of our common stock under the Ignyta Plan, with a weighted average exercise price of $4.41 per share.

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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 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, 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.

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 clinical-stage company with no approved products, and have generated no revenue to date and may never generate revenue or achieve profitability.

We are a clinical-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, 2012 and for the three and nine months ended September 30, 2013 was $1.3 million, $1.2 million and $3.4 million, respectively. As of September 30, 2013, we had an accumulated deficit of $4.8 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 our in-licensed clinical and preclinical product candidates RXDX-101 and RXDX-102 and our discovery stage programs 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 the Initial Private Placement for gross proceeds to us of approximately $46.4 million, and on November 29, 2013, we closed the Subsequent Private Placement 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 (SVB), which loan is discussed in more detail under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations elsewhere in this prospectus. Even after giving effect to the proceeds received from the Private Placements and the loan from SVB, we will require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner 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 Phase I/II clinical trial of RXDX-101 and prepare for and initiate a Phase I clinical trial of RXDX-102, and continue research and development and initiate additional clinical trials of, and seek regulatory approval for, these and other product candidates. In

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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 to investors in those offerings, which equals approximately 66.57% of our currently issued and outstanding capital stock. If we raise additional capital through the incurrence of further indebtedness, as we have done with our loan from SVB, we would likely become subject to 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;

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;

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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 (the New Loan Agreement). We are obligated to make payments under the New 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 New 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 New Loan Agreement contains various restrictive covenants, such as our obligation to deliver to SVB certain financial and insurance information and comply with certain notice requirements and our inability, 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 New Loan Agreement when due, would cause us to be in default under the New 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 pay 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.

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 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

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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 will 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 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 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, and we believe the matter may have been abandoned. We would vigorously defend any claims that may be pursued relating to this matter.

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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 U.S. Food and Drug Administration (FDA) or the European Medicines Agency (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 two early-stage lead product candidates, both of 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 lead product candidates. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize these two product candidates. One of our product candidates, RXDX-101, is in clinical trials, while our second product candidate, RXDX-102, is in preclinical development. 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.

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 has not yet commenced, and the results of any future preclinical or clinical studies, 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 lead 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 are in the process of assuming full control of preclinical and clinical studies relating to those product candidates, and we expect to assume full control in the first quarter of 2014. However, because we had no input on NMS development activities relating to these product candidates, we may discover that all or certain elements of the trials and studies it performed have not been in compliance with applicable regulatory standards or have otherwise been deficient. For instance, the development of each of our lead 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 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 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.

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. The specific line of our 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 drug 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 preclinical studies and initial clinical trials. For example, although the preclinical and early clinical results for our lead product candidates have 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, of which we are in the process of assuming control, and although we are planning to initiate clinical trials for RXDX-102 as early as 2014, 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 (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;
- obtaining approval from an independent institutional review board (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 drug 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. For example, enrollment for the Phase I/II clinical trial of RXDX-101 has been slow because of delays in recruiting suitable patients. 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.

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.

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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, the planned Phase I clinical trial of RXDX-102 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 (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;
- 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, RXDX-102 or any other product candidates we may seek to develop in the future, which would significantly harm our business, results of operations and prospects.

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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 price we intend 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.

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. While we have not yet initiated clinical trials for RXDX-102, as is the case with many oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials for these or 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.

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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 strat