Ignyta, Inc.
Form 10-Q
November 09, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2015

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-36344

Ignyta, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-3174872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11111 Flintkote Avenue, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 255-5959

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

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 definition 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 x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The number of outstanding shares of the registrant s common stock, par value $0.0001 per share, as of October 30, 2015, was 29,619,706.

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IGNYTA, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

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PART I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Ignyta, Inc.

Condensed Balance Sheets

	September 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 57,567,420	$ 6,345,663
Short-term investment securities	81,412,474	63,200,563
Prepaid expenses and other current assets	4,099,651	1,731,521
Total current assets	143,079,545	71,277,747
Long-term investment securities	24,126,863	7,086,700
Fixed assets, net	7,587,792	6,280,909
Other assets	539,624	658,716
Total assets	$ 175,333,824	$ 85,304,072
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 3,246,441	$ 975,264
Accrued expenses and other liabilities	6,951,067	4,929,601
Note payable, current portion	4,305,555	1,400,000
Lease payable, current portion	178,349	171,638
Total current liabilities	14,681,412	7,476,503
Note payable, net of current portion and discount	25,746,391	18,830,136
Lease payable, net of current portion	209,574	344,188
Other long-term liabilities	2,625,218	2,705,319
Total liabilities	43,262,595	29,356,146
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par; 10,000,000 shares authorized; no shares issued or outstanding		
Common stock, $0.0001 par; 150,000,000 shares authorized; 29,619,706 and 19,584,769 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	2,962	1,958
Additional paid-in capital	238,889,648	111,561,894

Accumulated deficit	(106,809,799)	(55,562,586)
Accumulated other comprehensive loss	(11,582)	(53,340)
Total stockholders equity	132,071,229	55,947,926
Total liabilities and stockholders equity	$ 175,333,824	$ 85,304,072

The accompanying notes are an integral part of these condensed financial statements.

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Ignyta, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenue	$	$	$	$ 150,000
Operating expenses:				
Research and development	10,432,392	8,622,547	39,444,281	14,380,914
General and administrative	3,856,451	2,223,311	10,477,542	6,023,580
Total operating expenses	14,288,843	10,845,858	49,921,823	20,404,494
Loss from operations	(14,288,843)	(10,845,858)	(49,921,823)	(20,254,494)
Other income (expense):				
Interest expense	(580,018)	(251,780)	(1,784,938)	(749,087)
Other income (expense)	247,975	394,385	459,548	771,014
Total other income (expense)	(332,043)	142,605	(1,325,390)	21,927
Net loss	$ (14,620,886)	$ (10,703,253)	$ (51,247,213)	$ (20,232,567)
Net loss per share - basic and diluted	$ (0.49)	$ (0.55)	$ (2.02)	$ (1.13)
Weighted average shares basic and diluted	29,601,363	19,579,588	25,365,025	17,905,134
Comprehensive loss:				
Net loss	$ (14,620,886)	$ (10,703,253)	$ (51,247,213)	$ (20,232,567)
Unrealized gains (losses) on available-for-sale securities	63,208	(45,988)	41,758	(40,426)
Comprehensive loss	$ (14,557,678)	$ (10,749,241)	$ (51,205,455)	$ (20,272,993)

The accompanying notes are an integral part of these condensed financial statements.

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Ignyta, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine months ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (51,247,213)	$ (20,232,567)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development charge associated with asset acquisition	11,880,000	
Stock-based compensation	3,431,059	1,517,503
Depreciation and amortization of fixed assets	1,255,269	257,839
Accretion and amortization on investment securities	1,115,263	560,188
Amortization of non-cash financing costs	404,159	219,327
Other	(346)	27,537
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	(2,141,157)	(192,208)
Accounts payable	2,271,177	(13,672)
Accrued expenses and other liabilities	1,641,365	1,942,748
Net cash used in operating activities	(31,390,424)	(15,913,305)
Cash flows from investing activities:		
Purchases of investment securities	(116,907,550)	(79,419,409)
Maturities and sales of investment securities	80,260,278	5,674,868
Purchases of fixed assets	(2,561,806)	(1,996,753)
Net cash used in investing activities	(39,209,078)	(75,741,294)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	111,588,519	51,581,843
Proceeds from issuance of notes payable	10,000,000	21,000,000
Payments of debt issuance costs		(155,000)
Proceeds from exercise of stock options	360,643	5,472
Payments on notes and leases payable	(127,903)	(10,000,000)
Payments of deferred financing costs		(1,050,000)
Repurchase of common stock		(1,440)
Net cash provided by financing activities	121,821,259	61,380,875
Net change in cash and cash equivalents	51,221,757	(30,273,724)
Cash and cash equivalents at beginning of period	6,345,663	51,803,716

Cash and cash equivalents at end of period	$ 57,567,420	$ 21,529,992
Supplemental disclosures of cash flow information:		
Interest paid	$ 1,368,173	$ 1,574,767
Noncash investing and financing activities:		
Final loan fee and issuance of warrants recorded as debt discount	$ 368,536	$ 838,400
Assets acquired under capital leases	$	$ 170,000
Leasehold improvements paid for by landlord	$	$ 100,000
Unrealized gain (loss) on available-for-sale securities	$ 41,758	$ (40,426)

The accompanying notes are an integral part of these condensed financial statements.

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Ignyta, Inc.

Notes to Condensed Financial Statements

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization and Nature of Operations

Ignyta, Inc. (Ignyta or the Company) is incorporated in the state of Delaware and was founded in 2011 (with the name NexDx, Inc.). The Company changed its name to Ignyta, Inc. on October 8, 2012. The Company is a precision oncology biotechnology company dedicated not just to shrinking tumors but to eradicating residual disease the source of cancer relapse and recurrence in precisely defined patient populations. The Company is pursuing an integrated therapeutic (Rx) and companion diagnostic (Dx) strategy for treating cancer patients. Its Rx efforts are focused on discovering, in-licensing or acquiring, then developing and commercializing molecularly targeted therapies; cancer stem cell/dormant tumor cell targeted therapies; novel chemotherapies/cell cycle inhibitors; and cancer immunotherapies four therapeutic cornerstones that, sequentially or in combination, are foundational for eradicating residual disease. Its Dx efforts aim to pair these product candidates with biomarker-based companion diagnostics that are designed to precisely identify, at the molecular level, the patients who are most likely to benefit from the monotherapies and polytherapies it develops.

On October 31, 2013, the Company merged with and into IGAS Acquisition Corp., a wholly owned subsidiary of Ignyta, Inc., a Nevada corporation previously named Infinity Oil & Gas Company (Parent), formerly a shell company under applicable rules of the Securities and Exchange Commission (the SEC). The Company changed its name to Ignyta Operating, Inc. in connection with this merger, and it survived the merger as a wholly owned subsidiary of Parent. In the merger, Parent acquired the business of the Company and continued the business operations of the Company. The merger was accounted for as a reverse merger and recapitalization, with the Company as the acquirer and Parent 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 the Company and are recorded at the historical cost basis of the Company, and the consolidated financial statements after completion of the merger will include the assets and liabilities of Parent and the Company, the historical operations of the Company and the operations of the combined enterprise of Parent and the Company from and after the closing date of the merger. On June 12, 2014, Parent merged with and into the Company, with the Company surviving the merger and changing its name to Ignyta, Inc. (the Reincorporation Merger). This Reincorporation Merger had no material impact on the accounting of the company.

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, the instructions to Form 10-Q and related SEC rules and regulations. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management s opinion, the accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results for the interim periods presented. Interim financial results are not necessarily indicative of results anticipated for the full year. These unaudited financial statements should be read in conjunction with the Company s audited financial

statements and footnotes included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Liquidity

The Company had negative cash flow from operations of approximately $31.4 million during the first nine months of 2015 and, as of September 30, 2015, had an accumulated deficit of approximately $106.8 million. The Company is focused primarily on its development programs, and management believes such activities will result in the continued incurrence of significant research and development and other expenses related to those programs. The Company expects that it will need additional capital to further fund development of, and seek regulatory approvals for, its product candidates, and begin to commercialize any approved products. If the clinical trials for any of the Company s products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of its product candidates, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if it achieves profitability in the future, the Company may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash on hand and through additional financing from existing and prospective investors. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or to its stockholders.

As of September 30, 2015, the Company had cash, cash equivalents and investment securities totaling $163.1 million. While the Company expects that its existing cash, cash equivalents and investment securities will enable it to fund its operations and capital expenditure requirements for at least the next twelve months, having insufficient funds may require the Company to delay, reduce, limit or terminate some or all of its development programs or future commercialization efforts or grant rights to develop and market

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product candidates that it would otherwise prefer to develop and market on its own. Failure to obtain adequate financing could eventually adversely affect the Company s ability to operate as a going concern. If the Company raises additional funds from the issuance of equity securities, substantial dilution to its existing stockholders would likely result. If the Company raises additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict its ability to operate its business.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Actual results could differ from those estimates. Significant estimates used in preparing the financial statements include those assumed in estimating expenses for the Company s pre-clinical studies and clinical trials, computing the valuation allowance on deferred tax assets, and calculating stock-based compensation expense.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less when purchased to be cash equivalents. Cash equivalents primarily represent amounts invested in money market funds whose cost equals market value.

Investment Securities

Investment securities consist of government and government agency obligations, corporate notes and bonds and commercial paper. The Company classifies its investment securities as available-for-sale at the time of purchase. All investment securities are recorded at estimated fair value. Unrealized gains and losses for available-for-sale investment securities are included in accumulated other comprehensive income, a component of stockholders equity.

The Company evaluates its investment securities as of each balance sheet date to assess whether those with unrealized loss positions are other-than-temporarily impaired. Impairments are considered to be other-than-temporary if they are related to deterioration in credit risk or if it is likely that the Company will sell the securities before the recovery of its cost basis. Realized gains and losses and declines in value judged to be other-than-temporary are determined based on the specific identification method. No other-than-temporary impairment charges have been recognized since inception.

Fair Value of Financial Instruments

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company s financial instruments consist of cash and cash equivalents, investment securities, prepaid expenses and other assets, accounts payable, accrued expenses, and notes payable. The valuation of assets and liabilities is subject to fair value measurements using a three tiered approach, and fair value measurement is classified and disclosed in one of the following categories:

Level 1:	Quoted prices in active markets for identical assets or liabilities;
Level 2:	Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
Level 3:	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Fair value estimates of these instruments at a specific point in time are made based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with precision.

The book values of all cash and cash equivalents, prepaid expenses and other assets, accounts payable, accrued expenses and notes payable are reasonable estimates of their fair values because of the short nature of these items. The Company reports its available-for-sale securities at their estimated fair values based on quoted market prices for identical or similar instruments.

Credit Risk

Cash is invested in accordance with a policy approved by the Company s board of directors which specifies the categories, allocations, and ratings of securities that the Company may consider for investment. Management does not believe that the Company s cash, cash equivalents and available-for-sale investment securities have significant risk of default or illiquidity. This determination is based on

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discussions with the Company s treasury managers and a review of the Company s holdings. While the Company believes that its cash, cash equivalents and available-for-sale investment securities are well diversified and do not contain excessive risk, the Company cannot provide absolute assurance that its investments will not be subject to future adverse changes in market value.

The Company maintains cash balances at various financial institutions. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. At times these balances exceed federally insured limits. The Company has not experienced any losses in such accounts. With respect to the Company s cash equivalents and available-for-sale investment securities, the primary exposure to market risk is interest rate sensitivity. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if the Company purchases a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of this investment will probably decline. Currently, the Company s holdings are in money market funds and available-for-sale investment securities, and therefore this interest rate risk is minimal. To minimize interest rate risk going forward, the Company intends to continue to maintain its portfolio of cash equivalents and available-for-sale investment securities in a variety of securities consisting of money market funds and debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. The Company also attempts to time the maturities of its investments to correspond with expected cash needs, allowing it to avoid realizing any potential losses from having to sell securities prior to their maturities.

Clinical Trial and Pre-Clinical Study Accruals

The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances known to it at that time. Accrued expenses for pre-clinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, clinical trial investigational sites, and other clinical trial-related vendors. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of milestones. In accruing service fees, management estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other information available to it. If the Company underestimates or overestimates the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in the Company s accruals.

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of (i) external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants; (ii) employee-related expenses, including salaries, benefits, travel and stock compensation expense; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies, and (v) license fees and other expenses relating to the acquisition of rights to our development programs.

The Company enters into consulting, research and other agreements with commercial firms, researchers, universities and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and

payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to the Company by its clinical sites and vendors and other information. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Stock-Based Compensation

Stock-based compensation cost for equity awards to employees and members of the Company s board of directors is measured at the grant date, based on the calculated fair value of the award using the Black-Scholes option-pricing model, and is recognized as an expense, under the straight-line method, over the requisite service period (generally the vesting period of the equity grant). Stock options issued to non-employees are accounted for at their estimated fair values determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as an expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

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Net Loss per Share

Basic and diluted loss per common share have been computed by dividing the losses applicable to common stock by the weighted average number of common shares outstanding. The Company s basic and fully diluted loss per common share calculations are the same since the increased number of shares that would be included in the diluted calculation from the assumed exercise of stock equivalents would be anti-dilutive to the net loss in each of the years shown in the financial statements.

The calculations of net loss per share excluded potentially dilutive securities (consisting of outstanding options, warrants, restricted stock and restricted stock units) of approximately 5.0 million and 3.2 million shares as of September 30, 2015 and 2014, respectively.

Recent Accounting Pronouncements

In April 2015, the FASB issued an accounting standard update, or ASU, which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet. The update does not change the guidance on the recognition and measurement of debt issuance costs. The Company intends to adopt this guidance at the beginning of its first quarter of fiscal 2016. At the time of adoption, the Company will reclassify debt issuance costs to a liability as a direct deduction from the carrying value of the debt, consistent with the presentation of a debt discount. The Company does not expect that the adoption of this update will have a material impact on its financial statements.

In August 2014, the FASB issued an ASU that requires management to evaluate whether there are conditions or events that raise substantial doubt about the entity s ability to continue as a going concern, and to provide certain disclosures when it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. Since this guidance is primarily around certain disclosures in the financial statements, the Company anticipates no impact on its financial position or results of operations from adopting this standard. The Company intends to adopt this guidance at the beginning of its first quarter of fiscal year 2016.

In May 2014, the FASB issued an ASU that supersedes or replaces nearly all revenue recognition guidance. The new guidance establishes a new control-based revenue recognition model, changes the basis for deciding when revenue is recognized over time or at a point in time and will expand disclosures about revenue. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its financial statements. This ASU is effective for the fiscal year beginning January 1, 2019. Early adoption is not permitted.

Reclassifications.

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. This change had no impact on the Company s reported net loss or its total assets.

3. INVESTMENT SECURITIES

The following tables summarize the investment securities held by the Company (as of the dates indicated):

	As of September 30, 2015 (in thousands)			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale securities:				
Commercial paper, short-term	$ 7,982	$	$	$ 7,982
Corporate debt securities, short-term	73,467	20	(57)	73,430
Corporate debt securities, long-term	21,098	26	(2)	21,122
U.S. government and agency obligations, long-term	3,004	1		3,005
Total	$ 105,551	$ 47	$ (59)	$ 105,539

	As of December 31, 2014 (in thousands)			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale securities:				
Commercial paper, short-term	$ 3,896	$	$	$ 3,896
Corporate debt securities, short-term	59,343		(38)	59,305
Corporate debt securities, long-term	7,102		(15)	7,087
Total	$ 70,341	$	$ (53)	$ 70,288

All of the Company s available-for-sale investment securities held at September 30, 2015 had maturity dates of less than 24 months. The Company determines the appropriate designation of investments at the time of purchase and reevaluates such designation as of each balance sheet date. Investment securities classified as short-term investments have maturity dates of less than one year from the balance sheet date, while securities classified as long-term investments have maturity dates of greater than one year from the balance sheet date. The cost of securities sold is based on the specific identification method. Amortization of premiums, accretion of discounts, interest, dividend income, and realized gains and losses are included in investment income.

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None of the Company s available-for-sale investment securities was in a material unrealized loss position at September 30, 2015. The Company reviewed its investment holdings as of September 30, 2015 and determined that its unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that no securities have been in an unrealized loss position for twelve months or more. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale securities.

The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during 2015 or 2014.

4. FAIR VALUE MEASUREMENTS

The Company holds available-for-sale securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its available-for-sale securities based upon one or more valuations reported by its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets or liabilities (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

The fair value of the Company s cash, cash equivalents and available-for-sale investment securities were as follows:

	As of September 30, 2015 (in thousands)				**As of December 31, 2014** (in thousands)			
	Level 1	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents	$ 57,567	$	$	$ 57,567	$ 6,346	$	$	$ 6,346
Short-term investments:								
Commercial paper		7,982		7,982		3,896		3,896
Corporate debt securities		73,430		73,430		59,305		59,305
Total short-term investments		81,412		81,412		63,201		63,201
Long-term investments:								
Corporate debt securities		21,122		21,122		7,087		7,087
U.S. government and U.S. government agency obligations	3,005			3,005				
Total long-term investments	3,005	21,122		24,127		7,087		7,087
Total assets measured at fair value	$ 60,572	$ 102,534	$	$ 163,106	$ 6,346	$ 70,288	$	$ 76,634

5. FIXED ASSETS

Fixed assets are recorded at cost and consisted of the following as of the dates indicated:

	September 30, 2015	December 31, 2014
Manufacturing and lab equipment	$ 6,166,096	$ 3,837,967
Leasehold improvements	2,348,897	2,326,963
Computer equipment and software	606,338	471,415
Office furniture	355,715	278,895
Fixed assets, gross	9,477,046	6,915,240
Less accumulated depreciation and amortization	(1,889,254)	(634,331)
Fixed assets, net	$ 7,587,792	$ 6,280,909

Depreciation and amortization expense is computed using the straight-line method over the estimated useful lives of the related assets. Depreciation and amortization expense was $462,064 and $1,255,269 for the three and nine months ended September 30, 2015, respectively, and $146,131 and $257,839 for the three and nine months ended September 30, 2014, respectively.

The net book value of the Company s equipment under capital leases was $523,655 as of September 30, 2015, which reflected accumulated life-to-date depreciation of $112,075. Depreciation expense on this equipment totaled $31,787 and $95,360 for the three and nine months ended September 30, 2015, respectively. These assets were acquired late in the fourth quarter of 2014, and as such, there was no depreciation expense reflected in the Company s operating results for the three and nine months ended September 30, 2014, related to these assets.

Remaining minimum payments under capital leases totaled $409,994 as of September 30, 2015.

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6. NOTE PAYABLE

In September 2014, the Company entered into an amended and restated loan agreement (the New Loan Agreement) with Silicon Valley Bank (SVB), under which it incurred $21.0 million of indebtedness, approximately $11.0 million of which was used to repay the then-existing loan with SVB. In September 2015, the Company borrowed an additional $10.0 million under this agreement. The Company is required to pay interest on the borrowings under the amended and restated loan agreement at a fixed, per-annum rate of 8.6% on a monthly basis through April 30, 2016. The loan principal will be repaid in 36 equal monthly payments commencing May 1, 2016, such that the loan will be fully paid by April 1, 2019. The Company will also owe the lender a final payment of $930,000 at loan maturity. This final payment is presented as a debt discount which is being amortized to interest expense over the term of the loan. The Company may elect to prepay all amounts owed prior to the maturity date, provided that a prepayment fee equal to 1.0% of the amount prepaid is also paid.

In connection with this agreement, the Company issued to SVB and its affiliate warrants to purchase an aggregate of 53,281 shares of its common stock. The fair value of these warrants has been recorded as a debt discount and is being amortized to interest expense over the term of the New Loan Agreement.

Future minimum principal payments under the Company s note payable are as follows as of September 30, 2015:

Year ending December 31,	*Minimum Payments*
2015 (3 months)	$
2016	6,888,889
2017	10,333,333
2018	10,333,333
2019	3,444,445
Total	$ 31,000,000

Pursuant to the New Loan Agreement, the Company is bound by certain affirmative and negative covenants setting forth actions that it must and must not take during the term thereof. Upon the occurrence of an event of default under the New Loan Agreement, subject to cure periods for certain events of default, all amounts owed by the Company thereunder shall begin to bear interest at a rate of 11.6% and may be declared immediately due and payable by SVB. The Company has granted SVB a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed to SVB under the New Loan Agreement. The Company has also agreed not to encumber any of its intellectual property without SVB s written consent.

7. ASSET ACQUISITION

On March 17, 2015, under the terms of an asset purchase agreement with Cephalon, Inc. (Cephalon), an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. (Teva), the Company acquired certain assets relating to four oncology development programs. The development programs that were purchased from Teva include:

RXDX-105, an orally available, small molecule multikinase inhibitor with potent activity against such key targets as RET and BRAF that is currently in a Phase I/Ib dose escalation clinical trial;

RXDX-107, a new chemical entity comprising an alkyl ester of bendamustine encapsulated in human serum albumin (HSA) to form nanoparticles that is in a Phase I/Ib dose escalation clinical trial;

RXDX-106, a small molecule, pseudo-irreversible inhibitor of TYRO3, AXL, Mer (TAM) and cMET that is in late preclinical development; and

RXDX-108, a small molecule inhibitor of the atypical kinase PKCiota that is in preclinical studies. The Company also acquired certain next generation PKCiota inhibitors in addition to the lead compound.

Under the asset purchase agreement, the Company acquired Cephalon s right, title and interest in and to certain intellectual property, compounds, products, contracts, records, data and development supplies related to these programs (the Purchased Assets), and assumed certain related commitments. The Company did not acquire any marketable products, established customer or employee bases, or any established business, management, operational or resource management processes. Accordingly, the Company recorded this transaction as an asset purchase as opposed to a business combination. As consideration for the Purchased Assets, the Company issued to Cephalon 1,500,000 unregistered shares of the Company s common stock and assumed certain other third-party obligations (see Note 8).

The acquired assets are in various stages of drug development, ranging from preclinical stage to Phase I clinical trials. As such, the development plans are still being formulated and are as yet incomplete. The Company will be conducting further preclinical studies and making continued assessments of potential and actual clinical development plans related to these compounds. As the success of the Company s commercialization of these acquired compounds remains uncertain and the assets in question have no alternative future uses, the Company recorded an in-process research and development charge of approximately $11.9 million during the first quarter of 2015 based on the value of the net assets exchanged for the Teva assets.

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Under the provisions of the asset purchase agreement, the Company paid approximately $0.9 million to Cephalon for drug development supplies, which was included in research and development expenses for the first quarter of 2015. Concurrent with the above transaction, Cephalon also entered into a subscription agreement with the Company whereby Cephalon agreed to purchase an additional 1,500,000 shares of the Company s common stock at a price of $10.00 per share (see Note 10).

In connection with the asset purchase agreement, the Company entered into a registration rights agreement with Cephalon pursuant to which the Company has agreed to register the shares of the Company s common stock held by Cephalon. The Company has filed a registration statement with the SEC relating to such shares, and the SEC has declared the registration statement effective. The Company may be liable for liquidated damages if it fails to maintain the effectiveness of the registration statement, subject to certain exceptions. The amount of the liquidated damages per applicable thirty-day period is one percent of the aggregate purchase price of the registrable securities then held by each holder, subject to an aggregate cap of ten percent. The Company also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement and payment of certain expenses.

8. LICENSE AGREEMENTS

Entrectinib

The Company entered into a license agreement with Nerviano Medical Sciences S.r.l. (NMS) on October 10, 2013, which was amended on October 25, 2013, became effective on November 6, 2013, and was amended December 12, 2014. The agreement grants the Company exclusive global rights to develop and commercialize entrectinib, as well as a second product candidate, RXDX-102. Based on clinical trial results relating to entrectinib that have been seen to date, the Company designated RXDX-102 as a back-up compound to entrectinib. Accordingly, the Company will not devote further development resources to RXDX-102. The Company s development rights under the license agreement are exclusive for the term of the agreement with respect to entrectinib and RXDX-102 and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with activity against the target proteins of entrectinib and RXDX-102, and include the right to grant sublicenses. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on either or both of entrectinib and RXDX-102, at its expense.

The terms of the license agreement provided for an up-front payment to NMS of $7.0 million, which was paid in November 2013 and expensed as research and development (as no future benefit was determined to exist at that time). When and if commercial sales of a product based on either or both of entrectinib or RXDX-102 begin, the Company will be obligated to pay NMS tiered royalties ranging from a mid-single digit percentage to a low double digit percentage (between 10% and 15%) of net sales, depending on the amount of net sales, with standard provisions for royalty offsets to the extent it obtains any rights from third parties to commercialize the product. The Company was also obligated under the terms of the license agreement to engage NMS to perform services valued at $1.0 million prior to December 31, 2014, which obligation had been met prior to that time. The license agreement also requires that the Company makes development and regulatory milestone payments to NMS of up to $105.0 million in the aggregate if specified clinical study initiations and regulatory approvals are achieved across multiple products or indications. Pursuant to the December 2014 amendment to the agreement, the Company paid the initial milestone payment of $10.0 million to NMS in December 2014, which was expensed as research and development (as no future benefit was determined to exist at that time).

RXDX-103 and RXDX-104

On August 4, 2014, the Company entered into a second license agreement with NMS. The agreement grants the Company exclusive global rights to develop and commercialize RXDX-103, as well as a second development program, RXDX-104. Based on preclinical activities relating to RXDX-104, in December 2014, the Company decided to discontinue development of RXDX-104, and the Company will not devote further development resources to this program. The Company has returned the rights to RXDX-104 to Nerviano. The Company s rights under the agreement are exclusive for the term of the agreement with respect to RXDX-103 and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with activity against the target proteins of RXDX-103, subject to NMS s right to develop and commercialize a predecessor compound to RXDX-103 solely for animal indications. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on RXDX-103, at its expense.

Under the license agreement, the Company made an up-front payment to NMS of $3.5 million in August 2014, which was expensed to research and development (as no future benefit was determined to exist at that time). When and if commercial sales of a product based on RXDX-103 begin, the Company will be obligated to pay NMS tiered royalties ranging from a mid-single digit percentage to a low double digit percentage of net sales, depending on annual amounts of net sales, with standard provisions for royalty offsets to the extent it is required to obtain any rights from third parties to commercialize RXDX-103. The Company is also required to make development and regulatory milestone payments to NMS of up to $67.25 million in the aggregate for RXDX-103 if specified clinical study initiations and regulatory approvals are achieved across multiple products or indications.

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RXDX-105 and RXDX-106

In connection with the March 2015 asset acquisition from Cephalon, the Company assumed all rights and obligations under the collaboration agreement dated November 3, 2006, as amended April 17, 2009, between Cephalon, Inc. and Daiichi Sankyo Company, Limited (Daiichi Sankyo), as successor-in-interest to Ambit Biosciences Corporation. The collaboration was for the purpose of identifying and developing clinical candidates that demonstrate activity towards the two designated target kinases of the collaboration: the BRAF kinase and the AXL kinase. Under the agreement, both parties contributed certain intellectual property to the collaboration and agreed to a period of exclusivity during which neither party would engage in any research related to a collaboration target compound with any third-party. The collaboration portion of the agreement ended in November 2009, but the agreement remains in effect on a product-by-product, country-by-country basis until all royalty obligations expire. Both parties have a right to terminate the agreement if the other party enters bankruptcy or upon an uncured breach by the other party. The Company may also terminate the agreement in its discretion upon 90 days written notice to Daiichi Sankyo. The Company is solely responsible for worldwide clinical development and commercialization of collaboration compounds, subject to the option of Daiichi Sankyo, exercisable during certain periods following completion of the first proof-of-concept study in humans and only with the consent of the Company, to co-develop and co-promote RXDX-105. If the Company decides to discontinue development of the RXDX-105 program, it must give written notice to Daiichi Sankyo, which will have the right to assume control of that program, subject to diligence obligations and payment of the milestones and royalties to the Company that would otherwise have been paid to Daiichi Sankyo had the Company maintained responsibility for the program.

The agreement requires the Company to make development, regulatory and sales milestone payments to Daiichi Sankyo of up to $44.5 million in the aggregate for RXDX-105, and up to $47.5 million in payments upon the achievement of development, regulatory and sales milestones for RXDX-106. When and if commercial sales of a product based on either of RXDX-105 or RXDX-106 begin, the Company will be obligated to pay Daiichi Sankyo tiered royalties ranging from a mid-single digit percentage to a low double digit percentage of net sales, depending on annual amounts of net sales, with standard provisions for royalty offsets to the extent it is required to obtain any rights from third parties to commercialize either RXDX-105 or RXDX-106. Royalties are payable to Daiichi Sankyo on a product-by-product, country-by-country basis beginning on the date of the first commercial sale in a country and ending on the later of 10 years after the date of such sale in that country or the expiration date of the last to expire licensed patent covering the product in that country.

RXDX-108

In connection with the March 2015 asset acquisition from Cephalon, the Company assumed all rights and obligations under the license agreement dated January 20, 2014, between Teva Branded Pharmaceutical Products R&D, Inc. and Cancer Research Technology Limited (CRT). The agreement grants the Company exclusive global rights to develop and commercialize RXDX-108. The Company also received rights to certain other next generation PKCiota inhibitors. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on RXDX-108 or the licensed intellectual property, at its expense. The agreement remains in effect on a product-by-product, country-by-country basis until all royalty obligations expire. Both parties have a right to terminate the agreement if the other party enters bankruptcy or upon an uncured breach by the other party. CRT may also terminate the agreement upon a change in control of the Company by a third party that develops, sells or manufactures tobacco products.

The license agreement requires the Company to make development, regulatory and sales milestone payments to CRT of up to $57.0 million in the aggregate. When and if commercial sales of a product based on the licensed intellectual property begin, the Company will be obligated to pay CRT tiered royalties ranging from a mid-single digit percentage

to a low double digit percentage of net sales, depending on annual amounts of net sales. Royalties are payable to CRT on a product-by-product, country-by-country basis beginning on the date of the first commercial sale in a country and ending on the later of 10 years after the date of such sale in that country or the expiration date of the last to expire licensed patent covering the product in that country.

9. COMMITMENTS AND CONTINGENCIES

The Company has entered into agreements with contract research organizations for clinical studies to be conducted both within and outside the U.S. for its product candidates. The total contracted cost under these arrangements is approximately $28.9 million as of September 30, 2015, of which approximately $10.7 million has been incurred to date. These agreements run through various dates, with the longest term expected to run through 2020. These contracts can be terminated at any time with no more than 60 days notice, at which point the Company would be obligated to pay for costs incurred though the termination date.

The Company leases office space and lab equipment under non-cancelable operating leases expiring on various dates through October 2019. Future minimum lease payments under the Company s operating leases totaled approximately $3.5 million as of September 30, 2015.

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10. STOCKHOLDERS EQUITY

Authorized Shares

The Company is authorized to issue 150,000,000 shares of common stock and 10,000,000 shares of preferred stock, with the preferred stock having the rights, preferences and privileges that the Company s board of directors may determine from time to time. Each share of the Company s common stock is entitled to one vote, and all shares rank equally as to voting and other matters.

Stock Offerings

In June 2015, the Company completed a public stock offering providing for the issuance and sale to investors of an aggregate of 4,285,714 shares of its common stock at a purchase price of $17.50 per share for net proceeds of approximately $70.1 million (after deducting transaction costs of $4.9 million).

In March 2015, concurrent with its asset acquisition agreement with Cephalon (see Note 7), the Company issued and sold 4,158,750 shares of common stock at $10.00 per share to Cephalon and several additional investors in a registered direct offering. The net proceeds from this offering totaled approximately $41.4 million (after deducting transaction costs of $149,000).

In March 2014, the Company completed a public stock offering providing for the issuance and sale to investors of an aggregate of 6,031,750 shares of its common stock at a purchase price of $9.15 per share for net proceeds of approximately $51.6 million (after deducting transaction costs of $3.6 million).

Warrants

Warrants to purchase up to an aggregate of 59,356 shares of the Company s common stock were outstanding as of September 30, 2015. These warrants have exercise prices ranging from $3.00 to $8.78 per share, and expire at various dates through September 2022.

Restricted Stock

The Company issued restricted shares in 2013 and 2011. The Company s restricted stock arrangements allow it to repurchase any unvested shares of stock in the event the holder ceases providing services to the Company. No shares have been repurchased by the Company during 2015. During 2014, the Company repurchased 400,000 restricted shares for $1,440.

Approximately 19,572 shares associated with restricted stock arrangements were subject to future vesting as of September 30, 2015.

11. EQUITY AWARDS

Equity Incentive Plans

The Company issues equity awards under its 2015 Employment Inducement Incentive Award Plan (the 2015 Inducement Plan) and its 2014 Incentive Award Plan (the 2014 Plan). The 2015 Inducement Plan provides for the issuance of up to 2,000,000 shares, while the 2014 Plan provides for the issuance of up to 3,000,000 shares, plus one additional share for each option share granted under the Company s 2011 Incentive Award Plan (the 2011 Plan) that

expires, is forfeited or is settled in cash subsequent to June 11, 2014. Both award plans allow for the issuance of awards to either employees or non-employees, however awards under the 2015 Inducement Plan may only be made to an employee who meets certain criteria (the award must be made in connection with commencement of employment and such award must be a material inducement to entering into employment). Prior to the adoption of the 2015 Inducement Plan and the 2014 Plan, the Company granted equity awards under the 2014 Employment Inducement Incentive Award Plan and the 2011 Plan. No additional equity grants may be made by the Company under either of these predecessor award plans. As of September 30, 2015, 2,219,058 shares remain available for grant under the Company s equity incentive plans.

A summary of the Company s equity incentive plan activity and other related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value
Balance at December 31, 2014	2,991,655	$ 6.67	9.21	$ 2,482,181
Granted	2,231,491	11.46		
Exercised	(71,102)	5.74		
Forfeited	(339,229)	7.42		
Balance at September 30, 2015	4,812,815	$ 8.85	8.85	$ 7,270,746
Exercisable at September 30, 2015	1,036,284	$ 5.96	8.98	$ 2,958,321

Options granted under the Company s equity plans are exercisable at various dates and will expire no more than ten years from their date of grant. The exercise price of each option to be granted under the 2015 Inducement Plan shall be determined by the administrator of the 2015 Inducement Plan, which is the compensation committee of the Company s board of directors, and shall not be less than 100% of the fair market value of the Company s common stock on the date the option is granted. For holders of more than 10% of the Company s total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the

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fair market value of the Company s common stock on the date of grant and for a term not to exceed five years. The exercise price of each option to be granted under the 2014 Plan shall be determined by the administrator of the 2014 Plan, which is the Company s board of directors or the compensation committee thereof, and shall not be less than 100% of the fair market value of the Company s common stock on the date the option is granted.

Fair Value of Equity Awards

The Company utilizes the Black-Scholes option pricing model to value awards under its plans. Key valuation assumptions include:

Volatility volatility is the measure of the amount by which a financial variable, such as a share price, has or is expected to fluctuate during a period. The Company considered the historical volatility of peer companies and business/ economic considerations in order to estimate expected volatility (as the Company not been publicly traded for a significant period).

Risk-Free Interest Rate this is the U.S. Treasury rate for the day of each option grant during the quarter having a term that most closely resembles the expected life of the option.

Dividend Yield the Company has never declared or paid dividends on common stock and has no plans to do so.

Expected Life of the Option Term this is the period of time that the options granted are expected to remain unexercised. Options granted during the period have a maximum contractual term of ten years. The Company estimates the expected life of the option term for employee option grants based on the simplified method (as defined in Staff Accounting Bulletin 110). For non-employee option grants, this is the remaining contractual term of the option.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company assesses the forfeiture rate on an annual basis and revises the rate when deemed necessary.

The fair value of option grants made during fiscal 2015 was estimated using the following weighted-average assumptions:

	Fiscal 2015
Volatility	67.6%
Risk free interest rate	1.66%
Dividend yield	0.00%
Expected life of option	6.2 years

The estimated weighted-average fair value of stock options granted during fiscal 2015 was $7.03 per share.

Stock-Based Compensation

The following table summarizes stock-based compensation expense for all equity awards to employees and non-employees during the periods presented:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Included in research and development	$ 651,396	$ 282,271	$ 1,567,608	$ 591,714
Included in general and administrative	675,879	417,902	1,863,451	925,789
Total	$ 1,327,275	$ 700,173	$ 3,431,059	$ 1,517,503

Unrecognized stock-based compensation expense related to unvested awards granted under the Company s equity incentive plans totaled $19.2 million as of September 30, 2015, and is expected to be recognized over a weighted-average period of 3.3 years.

Restricted Stock Units

In 2015, the Company issued 90,000 restricted stock units (RSUs) to employees with vesting to occur on either the fourth or fifth anniversary of the grant date. All of these RSUs were outstanding and subject to future vesting as of September 30, 2015.

12. SUBSEQUENT EVENTS

New Facility

On October 16, 2015, the Company entered into a commercial lease agreement that provides for the Company to lease approximately 95,146 square feet of office and laboratory space in two separate buildings in San Diego, California. The lease has a ten-year term, which is expected to commence in the fourth quarter of 2016. The base rent is initially set at $350,841 per month, although the first eight months of base rent will be abated. The base rent will increase by 3% annually, effective on the anniversary of the lease term commencement date. As is customary with similar lease arrangements, the Company will be responsible for a portion of the operating expenses of the complex in which the leased facilities are located. The lease contains a one-time provision to terminate the lease for all or a portion of the facilities, effective as of the end of the 72nd month after the lease commencement date, subject to the payment of a termination fee defined in the lease agreement. Minimum base rent payments over the non-cancellable lease term total $24.5 million.

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The facilities leased by the Company are currently undergoing significant renovation. The landlord will be responsible for the cost and completion of all landlord and tenant-requested improvements to the new facilities, subject to a cap on the amount of tenant-requested improvements. Upon completion of the renovation effort, the Company expects to relocate its operations to this site.

Amendment to Existing Facility Lease

On October 16, 2015, Ignyta also entered into an amendment to its existing facility lease providing for the Company to lease an additional 20,074 square feet of office and laboratory space commencing in January 2016 at a base rent of $55,204 per month. This agreement terminates 30 days after the commencement of the lease for the Company s new facility.

The term of the Company s existing facility lease extends through October 2019. Under the provisions of this amended agreement, the Company s existing facility lease will expire in stages beginning on the date which is 30 days after the commencement of the lease for the Company s new facility and ending on the date which is 300 days after the commencement of the lease for the Company s new facility.

Exclusive License from Eli Lilly and Company

On November 6, 2015, the Company entered into a license, development and commercialization agreement with Eli Lilly and Company (Lilly) under which the Company received exclusive, global rights to develop and commercialize pharmaceutical products under the licensed technology (Licensed Products), including Lilly s product candidate taladegib. Taladegib is a small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase II dose in a Phase I dose escalation trial. The Company granted back to Lilly an exclusive license to develop and commercialize pharmaceutical products comprising taladegib in combination with certain other molecules (Combination Products). The Company also licensed the exclusive worldwide rights to the topical formulation of taladegib, which is a late preclinical program being developed for the potential treatment of patients with superficial and nodular basal cell carcinoma.

The Company s rights under the agreement are exclusive for the term of the agreement. Both parties rights under the agreement include the right to grant sublicenses. The Company is obligated under the agreement to use commercially reasonable efforts to develop and commercialize Licensed Products, at its expense.

The terms of the license agreement provided for an up-front payment to Lilly of $2.0 million, plus the issuance to Lilly in a private placement of 1,213,000 shares of the Company s common stock. When and if commercial sales of Licensed Products begin, the Company will be obligated to pay Lilly a royalty of net sales. When and if commercial sales of Combination Products begin, Lilly will be obligated to pay the Company a royalty percentage of net sales. Both parties royalty obligations are subject to standard provisions for royalty offsets to the extent a party is required to obtain any rights from third parties to commercialize the applicable products, or in the event of loss of exclusivity or generic competition. The license agreement also requires that the Company makes development and sales milestone payments to Lilly of up to $38.0 million. The Company may elect to pay a portion of such amounts by issuing to Lilly shares of its common stock in a private placement, provided that the Company issues to Lilly an additional 15% of the number of shares issued to Lilly in connection with such election and subject to other conditions.

Both parties have a right to terminate the agreement if the other party enters bankruptcy, upon an uncured breach by the other party or if the other party challenges its patents relating to the licensed technology.

Concurrent with the above transaction, Lilly also entered into a stock purchase agreement with the Company whereby Lilly agreed to purchase an additional 1.5 million shares of the Company s common stock at a price of $20.00 per share for an aggregate purchase price of $30.0 million. The Company also entered into a registration rights agreement with Lilly pursuant to which the Company has agreed to register the resale of the shares of the Company s common stock held by Lilly. The Company may be liable for liquidated damages if it fails to timely file, obtain effectiveness or maintain the effectiveness of the registration statement.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014, and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2014. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption Risk Factors in the Annual Report on Form 10-K for the year ended December 31, 2014 and the caption Risk Factors in this Quarterly Report on Form 10-Q.

On October 31, 2013, we merged with and into IGAS Acquisition Corp., a wholly owned subsidiary of Ignyta, Inc., a Nevada corporation previously named Infinity Oil & Gas Company, or Parent, formerly a shell company under applicable rules of the Securities and Exchange Commission, or the SEC. We survived the merger as a wholly owned subsidiary of Parent. In the merger, Parent acquired our business and continued our business operations. The merger is accounted for as a reverse merger and recapitalization, with us as the acquirer and Parent 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 ours and are recorded at our historical cost basis, and the consolidated financial statements after completion of the merger will include the assets and liabilities of Parent and us, the historical operations of us and the operations of the combined enterprise of Parent and us from and after the closing date of the merger. As a result of the accounting treatment of the merger and the change in Parent s business and operations from a shell company to a precision oncology 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 is based on our financial statements. On June 12, 2014, Parent merged with and into us, with us surviving the merger and changing our name to Ignyta, Inc. This merger had no material impact on the accounting of the company. Unless the context indicates or otherwise requires, the terms we, us, our and our company refer to (i) Parent and us, its consolidated subsidiary, for discussions relating to periods before and through June 12, 2014, and (ii) us, the surviving company to the June 12, 2014 merger, for discussions relating to periods after June 12, 2014.

Overview

We are a precision oncology biotechnology company dedicated not just to shrinking tumors but to eradicating residual disease the source of cancer relapse and recurrence in precisely defined patient populations. We are pursuing an integrated therapeutic, or Rx, and companion diagnostic, or Dx, strategy for treating cancer patients. Our Rx efforts are focused on discovering, in-licensing or acquiring, then developing and commercializing molecularly targeted therapies; cancer stem cell/dormant tumor cell targeted therapies; novel chemotherapies/cell cycle inhibitors; and cancer immunotherapies four therapeutic cornerstones that, sequentially or in combination, are foundational for eradicating residual disease. Our Dx efforts aim to pair these product candidates with biomarker-based companion diagnostics that are designed to precisely identify, at the molecular level, the patients who are most likely to benefit from the monotherapies and polytherapies we develop.

Our current development plans focus on our pipeline:

- entrectinib, formerly called RXDX-101, a small molecule tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in a Phase II clinical

study and two Phase I clinical studies in molecularly defined patient populations for the treatment of solid tumors;

taladegib, a small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase II dose in a Phase I dose escalation trial;

RXDX-105, an orally available, small molecule multikinase inhibitor with potent activity against such targets as RET and BRAF, that is currently in a Phase I/Ib dose escalation clinical trial;

RXDX-107, a new chemical entity comprising an alkyl ester of bendamustine encapsulated in human serum albumin, or HSA, to form nanoparticles that is in a Phase I/Ib dose escalation study;

topical taladegib, a late preclinical development program for the potential treatment of patients with superficial and nodular basal cell carcinoma;

RXDX-106, a small molecule, pseudo-irreversible inhibitor of TYRO3, AXL and Mer, or collectively TAM, and cMET that is in late preclinical development;

RXDX-103, a small molecule inhibitor of the cell division cycle 7-related, or Cdc7, protein kinase that is currently at the development candidate stage; and

RXDX-108, a small molecule inhibitor program of the atypical kinase PKCiota that is in preclinical studies.

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We acquired exclusive global development and commercialization rights to entrectinib under a license agreement with Nerviano Medical Sciences S.r.l., or NMS, that became effective in November 2013, we acquired exclusive global development and commercialization rights to RXDX-103 under a license agreement with NMS that became effective in August 2014, we acquired our RXDX-105, RXDX-106, RXDX-107 and RXDX-108 development programs in an asset purchase transaction with Cephalon, Inc., an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., or Teva, in March 2015 and we acquired exclusive, global development commercialization rights to taladegib under a license agreement with Eli Lilly and Company, or Lilly, in November 2015. We are also pursuing our Spark discovery-stage programs, directed to emerging oncology targets.

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 and acquiring rights to 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.

Financial Operations Overview

Revenue

To date, we have not generated any material revenue from services, product sales or otherwise. 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:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, investigational sites and consultants;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies; and
- license fees and other expenses relating to our acquisition of rights to our development programs.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We do not track our employee and facility related research and development costs by project, as we typically use our employee and infrastructure resources across multiple research and development programs. We believe that the allocation of such costs would be arbitrary and would not be meaningful. We have not historically tracked external development costs by program as the majority of our development spend was focused on the development and clinical trials of entrectinib. We have contracted with clinical research organizations to manage our clinical trials under agreed upon budgets, with oversight by our clinical program managers. Any deviations from the budgets must be approved by us in writing, prior to commencement of the work. Our internal research and development costs are controlled through our internal budget and forecast process and subject to quarterly review and analysis of budget versus actual expenditures.

Research and development activities are central to our business model. Our research and development programs that we expect will be our focus in the immediate future consist of the development of our entrectinib, taladegib, RXDX-105, RXDX-107, RXDX-106, RXDX-103 and RXDX-108 programs, and drug discovery activities for the development of our Spark programs. All of those research and development programs are in the early stage, and since product candidates in later stages of development generally have higher development costs than those in earlier stages of development, we expect research and development costs relating to each of those programs to increase significantly for the foreseeable future. However, the successful development of any of our product candidates, or any others we may seek to pursue, is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development for our programs, or whether any of our product candidates will reach successful commercialization. We are also unable to predict when, if ever, any net cash inflows will commence from any of the product candidates we currently or may in the future pursue. This lack of predictability is due to the numerous risks and uncertainties associated with developing medicines, many of which, such as our ability to obtain

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approvals to market and sell those medicines from the FDA, and other applicable regulatory authorities, are beyond our control, including the uncertainty of:

- establishing an appropriate safety profile with toxicology studies to submit an IND to the FDA or comparable applications to foreign regulatory authorities;
- successful enrollment in and adequate design and completion of clinical trials;
- successful demonstration of an acceptable safety profile with clinically meaningful efficacy to achieve a favorable benefit/risk profile sufficient to obtain regulatory approval in one or more countries;
- receipt of marketing approvals from applicable regulatory authorities, including the FDA and comparable foreign authorities;
- establishing commercial manufacturing capabilities or, more likely, seeking to establish arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, including establishing an internal sales and marketing force and/or establishing relationships with third parties for such purpose;
- developing and commercializing, individually or with third-party collaborators, companion diagnostics; and
- a continued acceptable safety profile of the products following approval, if any.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and likelihood of success associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal, commercial and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to facilities expansion, the hiring of additional personnel and increased fees to outside consultants, lawyers and accountants, among other expenses. Additionally, increased costs associated with operating as a public company are expected to include expenses related to services associated with maintaining compliance with requirements of the SEC, insurance and investor relations costs.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which we have prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting periods. We base our estimates on historical experience and on various other factors and assumptions that we believe are reasonable under the circumstances at the time the estimates are made, the results of which form the basis for making judgments about the book values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We periodically evaluate our estimates and judgments, including those described in greater detail below, in light of changes in circumstances, facts and experience.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. Our significant accounting policies are described in more detail in the notes to our financial statements included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014.

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We believe the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments are as follows:

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of (i) external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants; (ii) employee-related expenses, including salaries, benefits, travel and stock compensation expense; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies; and (v) license fees and other expenses relating to our acquisition of rights to our development programs.

We enter into consulting, research and other agreements with commercial firms, researchers, universities and others for the provision of goods and services. Under such agreements, we may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by our clinical sites and vendors and other information. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on our behalf.

In certain circumstances, we are required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Clinical Trial and Pre-Clinical Study Accruals

We make estimates of accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Accrued expenses for pre-clinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by CROs, clinical trial investigational sites, and other clinical trial-related vendors. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of milestones. In accruing service fees, management estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

Stock-based compensation cost for equity awards to employees and members of our board of directors is measured at the grant date, based on the calculated fair value of the award using the Black-Scholes option-pricing model, and is recognized as an expense, under the straight-line method, over the requisite service period (generally the vesting period of the equity grant). Stock options issued to non-employees are accounted for at their estimated fair values determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the

related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

Investments

Investments consist of government and government agency obligations, corporate notes and bonds and commercial paper. We classify investments as available-for-sale at the time of purchase. All investments are recorded at estimated fair value. Unrealized gains and losses for available-for-sale securities are included in accumulated other comprehensive income, a component of stockholders equity. We evaluate our investments as of each balance sheet date to assess whether those with unrealized loss positions are other-than-temporarily impaired. Impairments are considered to be other-than-temporary if they are related to deterioration in credit risk or if it is likely that we will sell the securities before the recovery of our cost basis. Realized gains and losses and declines in value judged to be other-than-temporary are determined based on the specific identification method and are reported in other income (expense), net in the statement of operations. No other-than-temporary impairment charges have been recognized since inception.

Recently Issued Accounting Pronouncements

In April 2015, the FASB issued an accounting standard update, or ASU, which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet. The update does not change the guidance on the recognition and measurement of debt issuance costs. We intend to adopt this guidance at the beginning of our first quarter of fiscal 2016. At the time of adoption, we will reclassify debt issuance costs to a liability as a direct deduction from the carrying value of the debt, consistent with the presentation of a debt discount. We do not expect that the adoption of this update will have a material impact on our financial statements.

In August 2014, the FASB issued an ASU that requires management to evaluate whether there are conditions or events that raise substantial doubt about the entity s ability to continue as a going concern, and to provide certain disclosures when it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. Since this guidance is primarily around certain disclosures to the financial statements, we anticipate no impact on our financial position, results of operations or cash flows from adopting this standard. We intend to adopt this guidance at the beginning of our first quarter of fiscal year 2016.

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In May 2014, the FASB issued an ASU that supersedes or replaces nearly all revenue recognition guidance. The new guidance establishes a new control-based revenue recognition model, changes the basis for deciding when revenue is recognized over time or at a point in time and will expand disclosures about revenue. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. We are evaluating which transition approach to use and its impact, if any, on our financial statements. This ASU is effective for the fiscal year beginning January 1, 2018. Early adoption is not permitted.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the three months ended September 30, 2015 and 2014, together with the changes in those items in dollars (in thousands) and as a percentage:

	Three months ended September 30, 2015	2014	Dollar Change	Percentage Change
Operating expenses:				
Research and development	$ 10,432	$ 8,623	$ 1,809	21%
General and administrative	3,857	2,223	1,634	74%
Total operating expenses	14,289	10,846	3,443	32%
Loss from operations	(14,289)	(10,846)	(3,443)	32%
Other income (expense), net	(332)	143	(475)	(332)%
Net loss	$ (14,621)	$ (10,703)	$ (3,918)	37%

Research and Development Expense. Research and development expense increased by approximately $1.8 million for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014, an increase of 21%. The increase in research and development expenses during 2015 was primarily attributable to an increase in activities relating to development of entrectinib and our other product candidates, including the assets acquired from Teva in March 2015. We also incurred an increase between periods for personnel expenses related to hiring and engaging additional employees and consultants to help us advance our product candidates, and facilities related expenses as a result of the expansion of our leased facilities space.

General and Administrative Expense. General and administrative expenses increased by approximately $1.6 million for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014, an increase of 74%. The increase in general and administrative expenses was primarily attributable to increases in personnel costs and investor relations, audit, legal and intellectual property costs.

Other Income (Expense), net. Other expense, net increased by approximately $475,000 for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014. This increase was due to an increase in the interest expense on our loan obligation to Silicon Valley Bank, or SVB (resulting from the additional borrowings we made during the third quarter of 2014), offset in part by the additional interest income generated by our portfolio of available-for-sale securities (resulting from an increase in investable funds).

Comparison of the Nine Months Ended September 30, 2015 and 2014

The following table summarizes our results of operations for the nine months ended September 30, 2015 and 2014, together with the changes in those items in dollars (in thousands) and as a percentage:

	Nine months ended September 30, 2015	2014	Dollar Change	Percentage Change
Revenue	$	$ 150	$ (150)	(100)%
Operating expenses:				
Research and development	39,444	14,381	25,063	174%
General and administrative	10,478	6,024	4,454	74%
Total operating expenses	49,922	20,405	29,517	145%
Loss from operations	(49,922)	(20,255)	(29,667)	146%
Other income (expense), net	(1,325)	22	(1,347)	(6,123)%
Net loss	$ (51,247)	$ (20,233)	$ (31,014)	153%

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Revenue. We did not record any revenue for the nine months ended September 30, 2015. We recorded revenue of $150,000 for the comparable period of 2014 due to a one-time service fee for research services.

Research and Development Expense. Research and development expense increased by approximately $25.1 million for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014, an increase of 174%. During 2015, we recorded an in-process research and development charge of approximately $11.9 million representing the net value of the assets exchanged for the intellectual property assets acquired from Teva. The remaining increase in research and development expenses during 2015 was primarily attributable to an increase in activities relating to development of entrectinib and our other product candidates, including the assets acquired from Teva in March 2015. We also incurred an increase between periods for personnel expenses related to hiring and engaging additional employees and consultants to help us advance our product candidates, and facilities related expenses as a result of the expansion of our leased facilities space.

General and Administrative Expense. General and administrative expenses increased by approximately $4.5 million for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014, an increase of 74%. The increase in general and administrative expenses was primarily attributable to increases in personnel costs and investor relations, audit, legal and intellectual property costs.

Other Income (Expense), net. Other expense, net increased by approximately $1.3 million for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014. This increase was due to an increase in the interest expense on our loan obligation to SVB (resulting from the additional borrowings we made during the third quarter of 2014), offset in part by the additional interest income generated by our portfolio of available-for-sale securities (resulting from an increase in investable funds).

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, and through September 30, 2015, we have raised an aggregate of approximately $263.3 million to fund our operations, of which approximately $75.0 million was received from our issuance and sale of our common stock in an underwritten public offering in June 2015, approximately $41.6 million was raised through our issuance and sale of our common stock in a registered direct offering in March 2015, approximately $55.2 million was received from our issuance and sale of our common stock in an underwritten public offering in March 2014, approximately $54.1 million was received from our issuance and sale of our common stock in two private placements in November 2013, approximately $31.0 million was received from the incurrence of indebtedness under our loan agreements with SVB and approximately $6.0 million was received from our issuance and sale of our preferred stock. We had also received a small amount of funding from our issuance of common stock to our founders in August and September 2011, and from our issuance of common stock upon the exercise from time to time of stock options.

Public Offerings. In June 2015 and March 2014, we issued an aggregate of 10,317,464 shares of our common stock in underwritten public offerings. All of the shares issued in the June 2015 offering were sold at a purchase price per share of $17.50, and all of the shares issued in the March 2014 offering were sold at a purchase price per share of $9.15. The offerings generated aggregate gross proceeds of approximately $130.2 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately $121.7 million.

Registered Direct Offering. In March 2015 we issued an aggregate of 4,158,750 shares of our common stock in a registered direct offering. All of the shares issued in the offering were sold at a purchase price per share of $10.00 per

share, for aggregate gross proceeds of approximately $41.6 million and aggregate net proceeds, after deducting offering fees and expenses, of approximately $41.4 million.

Private Placements. In November 2013, we entered into securities purchase agreements with accredited investors providing for the issuance and sale to such investors of an aggregate of 9,010,238 shares of our common stock in private placement transactions. All of the shares issued in the private placements were sold at a purchase price per share of $6.00, for aggregate gross proceeds of approximately $54.1 million and aggregate net proceeds, after deducting placement agent and other offering fees and expenses, of approximately $51.0 million.

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Amended and Restated Loan Agreement with SVB. In September 2014, we entered into an amended and restated loan agreement with SVB, which was subsequently amended in June 2015, under which we incurred $21.0 million of indebtedness, approximately $11.0 million of which was used to repay our then-existing loan with SVB. In September 2015, we borrowed an additional $10.0 million under this agreement. We are required to pay interest on the borrowings under the amended and restated loan agreement at a fixed, per-annum rate of 8.6% on a monthly basis through April 30, 2016. Thereafter, we will be required to repay the principal plus interest in 36 equal monthly installments. Further, the terms of the amended and restated loan agreement require that we make a final lump-sum payment of 3.0% of the principal amount of the loans thereunder. We may elect to prepay all amounts owed under either or both of the loan tranches prior to the maturity date, provided that a prepayment fee is also paid (equal to 1.0% of the amount prepaid).

Pursuant to the amended and restated loan agreement, we are bound by certain affirmative and negative covenants setting forth actions that we must and must not take during the term thereof. Upon the occurrence of an event of default under the amended and restated loan agreement, subject to cure periods for certain events of default, all amounts owed by us thereunder shall begin to bear interest at a rate of 11.6% and may be declared immediately due and payable by SVB. We have granted SVB a security interest in substantially all of our personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed to SVB under the amended and restated loan agreement. We have also agreed not to encumber any of our intellectual property without SVB s prior written consent.

Preferred Stock Financings. We received approximately $6.0 million from the issuance and sale of our Series A and Series B preferred stock prior to the closing of our October 2013 merger. We received approximately $500,000 from our issuance and sale of an aggregate of 833,334 shares of our Series A preferred stock at a price per share of $0.60 to one investor in October 2011 and March 2012. We received approximately $5.5 million from our issuance and sale of an aggregate of 1,835,000 shares of our Series B preferred stock at a price per share of $3.00 to a number of investors in June 2012 and December 2012. On October 31, 2013, prior to the closing of the merger in which we became the wholly owned subsidiary of Parent, all then-outstanding shares of each series of our preferred stock were voluntarily converted by the holders thereof into shares of our common stock.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2015 and 2014 (amounts in thousands):

	Nine months ended, September 30,	
	2015	**2014**
Net cash used in operating activities	$ (31,390)	$ (15,913)
Net cash used in investing activities	(39,209)	(75,741)
Net cash provided by financing activities	121,821	61,381
Net increase in cash and cash equivalents	$ 51,222	$ (30,273)

Net Cash Used in Operating Activities. The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was approximately $31.4 million during the nine months ended September 30, 2015 compared to approximately $15.9

million during the same period of 2014. The increase in cash used in operating activities was driven primarily by an increase in activities relating to development of entrectinib and our other product candidates including the assets acquired from Teva in March 2015.

Net Cash Used in Investing Activities. Net cash used in investing activities was approximately $39.2 million during the nine months ended September 30, 2015 compared to approximately $75.7 million used by such activities during the same period of 2014, primarily reflecting investment activity associated with our available-for-sale securities and purchases of fixed assets.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was approximately $121.8 million during the nine months ended September 30, 2015, compared to approximately $61.4 million during the same period of 2014. The cash provided by financing activities during both periods was primarily the result of the funds raised through sales of our common stock and the net borrowings under our loan agreement with SVB.

Funding Requirements

We expect our expenses to continue to increase in the future in connection with the ongoing development of our entrectinib, taladegib, RXDX-105, RXDX-107, RXDX-106, RXDX-103 and RXDX-108 programs, and as we continue the research and development of our Spark programs. In addition, if we obtain marketing approval for any of our product candidates in the future, which we anticipate would not occur for several years, if at all, we expect we would then incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborators with whom we may engage.

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As of September 30, 2015, we had approximately $163.1 million in cash, cash equivalents and available-for-sale securities. We expect that our existing cash, cash equivalents and available-for-sale securities will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. We expect to need to obtain additional funding in future periods, however, in order to continue our operations and pursue our business plans. 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 future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our development programs;
- the scope, progress, results and costs of companion diagnostic development for our product candidates;
- the achievement of development milestones that trigger payments due to our licensing partners;
- the extent to which we acquire or in-license other medicines, biomarkers and/or technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval (to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of collaborators with whom we may engage);
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain development, manufacturing or commercial collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will likely need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us

on acceptable terms, or at all. We do not have any committed external sources of additional funds.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Any or all of those sources of funding may not be available when needed on acceptable terms, or at all. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the ownership interest of existing equity holders will be diluted. Also, the terms of any additional equity securities that may be issued in the future may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing may not be available when needed and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or relationships with third parties when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern.

Off-Balance Sheet Arrangements

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

Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue, anticipate, intend, seek, plan, expect,

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should or would, or the negative of these terms or other comparable terminology. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: 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 need for 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 obtain and, if obtained, maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate; our ability to retain or hire key scientific or management personnel; our ability, alone or 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, contract research organizations, testing laboratories and other potential collaborators; our ability to develop or avail ourselves of 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; regulatory developments in the United States and foreign countries; and other risks detailed under Part II Item 1A Risk Factors in this report and under Part I Item 1A Risk Factors in our most recent Annual Report on Form 10-K, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our cash, cash equivalents and available-for-sale investment securities as of September 30, 2015 consisted primarily of money market funds, government and government agency obligations, short-term commercial paper and corporate debt securities. We do not have any auction rate securities on our balance sheet, as they are not permitted by our investment policy. We maintain cash balances at various financial institutions. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. At times these balances exceed federally insured limits. We have not experienced any losses in such accounts.

With respect our available-for-sale securities, our primary exposure to market risk is interest rate sensitivity. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. Currently, our holdings are in money market funds and available-for-sale investment securities, and therefore this interest rate risk is minimal. To minimize interest rate risk going forward, we intend to continue to maintain our portfolio of cash, cash equivalents and available-for-sale investment securities in a variety of securities consisting of money market funds and debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. We also attempt to time the maturities of our investments to correspond with expected cash needs, allowing us to avoid realizing any potential losses from having to sell securities prior to their maturities.

Our cash is invested in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our

investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. We do not believe our cash, cash equivalents and available-for-sale investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash, cash equivalents and available-for-sale investment securities are well diversified and do not contain excessive risk, we cannot provide assurance that in the future our investments will not be subject to adverse changes in market value.

In addition, domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2015 at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2014 includes a detailed discussion of our risk factors under the heading Part I, Item 1A Risk Factors. Set forth below are certain changes from the risk factors previously disclosed in our Annual Report on Form 10-K. You should carefully consider the risk factors discussed in our Annual Report on Form 10-K as well as the other information in this report before deciding whether to invest in shares of our common stock. The occurrence of any of the risks discussed in the Annual Report on Form 10-K or this report could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective third party owners.

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 material revenue to date and may never generate material revenue or achieve profitability.

We are a development-stage biopharmaceutical company with a limited operating history. We have not generated any material 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, 2014 and the nine months ended September 30, 2015 was $40.0 million and $51.2 million, respectively. As of September 30, 2015, we had an accumulated deficit of $106.8 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 on the development of our clinical and preclinical development programs, which we believe will result in our continued incurrence of significant research and development and other expenses related to those programs. If the non-clinical or clinical trials for any of our product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fails 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 expect to need additional funding to continue our operations, which could result in 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, limit, reduce or terminate 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 our development programs 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.

Even after giving effect to the proceeds received from our common stock offerings and our loan arrangement with Silicon Valley Bank, or SVB, we expect to require substantial additional capital for the further development and commercialization of our product candidates. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to expand our ongoing entrectinib and other development programs, including our taladegib development programs we acquired from Eli Lilly and Company, or Lilly, in November 2015 and the four development programs we acquired from Cephalon, Inc., an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Limited, or Teva, in March 2015, and if we acquire rights to additional product candidates. For example, in September 2015 we initiated a new, global Phase II clinical trial of oral entrectinib in adult patients with advanced or metastatic cancer detected to be positive for relevant molecular alterations, as well as a new Phase I/Ib dose-escalation clinical trial of RXDX-107 in adult patients with locally advanced or metastatic solid tumors. In addition, in connection with our acquisition of assets from Teva, we assumed responsibility for an ongoing Phase I/Ib clinical trial of RXDX-105. We plan to initiate additional clinical trials to study our other product candidates in the future.

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 our growth, as well as operating as a public company. For example, in October 2015 we signed a new lease for approximately 95,000 square feet of office and laboratory space, and we expect this lease to become effective in the second half of 2016. 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 expect to need to obtain substantial additional funding in order to continue our operations.

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To date, we have financed our operations entirely through equity investments 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. If we raise additional capital through the incurrence of further indebtedness, as we have done under our loan agreement with 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 products.

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

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 September 30, 2014, we entered into an amended and restated loan agreement with SVB, which was subsequently amended on June 5, 2015, under which we incurred $21.0 million of indebtedness, approximately $11.0 million of which was used to repay our then-existing loan with SVB. In September 2015, we borrowed an additional $10.0 million under this agreement. We are required to pay interest on the borrowings under the amended and restated loan agreement at a fixed, per-annum rate of 8.6% on a monthly basis through April 30, 2016. Thereafter, we will be required to repay the principal plus interest in 36 equal monthly installments. The number of months of interest-only payments and the number of months over which the principal will be amortized was each increased by six months upon the consummation of our public offering of common stock in June 2015. Further, the terms of the amended and restated loan agreement require that we make a final lump-sum payment of 3% of the principal amount of the loans thereunder. We may elect to prepay all amounts owed under either or both of the loan tranches prior to the maturity date therefor, provided that a prepayment fee is also paid, equal to 1% of the amount prepaid.

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 amended and restated 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: 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 amended and restated loan agreement when due, would cause us to be in default. 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 or substantial amounts 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.

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 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 acquisition, 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.

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

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means that any of our employees could leave our employment at any time, with or without notice. 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, particularly in light of our March 2015 acquisition of four development programs from Teva and our November 2015 acquisition of rights to our taladegib development programs from Lilly.

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.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our current product candidates, 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 drug programs from NMS, Teva and Lilly. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize products resulting from these drug programs and any others we may acquire in the future, which may never occur.

Before we could generate any revenues from sales of our 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 clinical development;
- manage clinical, preclinical and manufacturing activities;
- achieve regulatory approvals;
- establish manufacturing relationships;
- build a commercial sales and marketing team, if we choose to market any such product ourselves, or enter into a collaboration to access sales and marketing functions;
- 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 our ongoing or planned clinical trials of entrectinib, taladegib, RXDX-105, RXDX-107 and our other product candidates are not successful, we may not be able to use those results as the basis for advancing these product candidates 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 these product candidates is not justified and may decide to discontinue the programs. If the results of preclinical testing for our other product candidates are not successful, we may not be able to use those results as the basis for advancing those programs into further development. If studies of our product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects could be substantially harmed, particularly if the product candidates for which development has ceased are at the clinical development stage.

Preclinical and clinical testing of our 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 acquired the rights to develop our programs from NMS, Teva and Lilly, and the previous development of those programs was conducted wholly by such companies or any third parties with which they had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. Because we had no input on those development activities, we may discover that all or certain elements of the trials and studies performed prior to our acquisition of rights to these programs have not been in compliance with applicable regulatory standards or have otherwise been deficient. If the previously conducted studies are not in full compliance with applicable regulatory standards or are otherwise not eligible for continued development in the United States or elsewhere, 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 could 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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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 earlier studies. For example, although the preclinical and early clinical results for our lead product candidate entrectinib have been promising, those results 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 are three clinical trials ongoing for entrectinib, one clinical trial ongoing for RXDX-105 and one clinical trial ongoing for RXDX-107, 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;

engaging leading clinical investigators to conduct or support our clinical trials;

clinical protocol design and development, and reaching consensus with participating investigators on study design;

reaching agreement on acceptable contractual and financial terms with prospective 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, or IRB, at each trial site;

enrolling suitable patients to participate in a trial;

developing and validating companion diagnostics on a timely basis, and utilizing such companion diagnostics on an effective and timely basis;

changes in formulation, dosing or administration regimens;

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

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

regulators instituting a clinical hold due to observed safety findings;

changes in the regulatory, clinical or commercial landscape during the conduct of a trial that impair accrual;

findings from nonclinical toxicology or safety pharmacology studies or the requirement for such studies;

adding new clinical trial sites; or

manufacturing or having manufactured sufficient quantities of product candidate and the stability of that product candidate for use in clinical trials on a timely basis.

We currently rely, and we expect to continue to rely, on CROs, clinical trial sites, contract manufacturers and other third parties to ensure the proper and timely conduct of our clinical trials. Although we have agreements in place with such third parties governing their committed activities and conduct, and we expect we will have similar agreements with other third parties 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 third party 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 third party 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 Monitoring Committee for the trial, if applicable, or by the FDA 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 sites by the FDA 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.

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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 entrectinib, taladegib, RXDX-105 and RXDX-107 have experienced some adverse events that are deemed to be drug related. Results of our ongoing or future clinical trials of these or our other product candidates could reveal a high and/or unacceptable severity and frequency of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA 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 could 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, 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 some of 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 product candidates. In June 2015, we announced the release for clinical use of our first clinical trial assay to support patient identification and enrollment into our Phase II clinical trial of entrectinib, but we have not developed or offered any companion diagnostics for commercial use. 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.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and 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 may partner in the future to develop and obtain clearance or approval for these companion diagnostics, and 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. We and our potential future collaborators may encounter difficulties in developing and obtaining 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, any 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.

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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 CROs we have engaged to continue the ongoing and planned clinical trials for entrectinib, taladegib, RXDX-105, and RXDX-107, 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 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 the agreements 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 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 affected product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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 currently have a limited supply of entrectinib and our other product candidates. We have a limited number of supply arrangements for entrectinib, and we are currently completely reliant on Teva for the clinical supply of RXDX-105 and RXDX-107. In addition, we have only a limited clinical supply of taladegib, and we must seek to establish clinical supply agreements with third parties for future supplies. We do not currently have arrangements in place for commercial supply of bulk drug substance or drug products. 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 preclinical or 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. If any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA 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.

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We expect to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our preclinical studies and clinical trials or for commercial sale. We do not have, nor do we expect to enter, any agreements for the 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 preclinical study or 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

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.

With respect to entrectinib, we are aware of two agents that have been approved by the FDA for ALK-positive NSCLC, Pfizer s Xalkori®/crizotinib and Novartis Zykadia®/ceritinib. In addition, Roche s alectinib is approved for this indication in Japan.

With respect to taladegib, we are aware of two agents that have been approved by the FDA to treat basal cell carcinoma and are designed to selectively inhibit the Hedgehog pathway by binding the Smoothened protein: Genentech s Erivedge®/vismodegib and Novartis Odomzo®/sonidegib.

With respect to RXDX-105, we are aware of three agents that have been approved by the FDA for BRAF-mutated melanoma, Genentech s Zelboraf®/vemurafenib and Novartis Tafinlar®/dabrafenib and Mekinist®/trametinib. Tafinlar®/dabrafenib and Mekinist®/trametinib are also approved for use as combination therapy. We are also aware of three agents that have been approved by the FDA for EGFR-mutated non-small cell lung cancer, Genentech s and Astellas Tarceva®/erlotinib, Boehringer Ingelheim s Gilotrif®/afatinib and AstraZeneca s Iressa®/gefitinib. In addition, Bristol-Myers Squibb s Erbitux®/cetuximab is approved by the FDA for EGFR-mutated head and neck cancer and colorectal cancer.

We are also aware of several other products in development targeting TrkA, TrkB, TrkC, ROS1, ALK, Hedgehog/Smoothened, RET, BRAF, EGFR, TYRO3, AXL, Mer, c-MET, CDC7 and/or aPKCiota, as well as new formulations of bendamustine and other alkylating agents, for the treatment of cancer, some of which may be in a more advanced stage of development than our product candidates. 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 our programs.

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. 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 of these or other factors, 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. Our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approvals, 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.

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.

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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, breach of warranties or other claims. Claims could also be asserted under state consumer protection acts or other laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit clinical testing of our product candidates or commercialization, 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 our clinical trials of entrectinib, taladegib, RXDX-105 and RXDX-107. 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. We could be responsible for some or all of the

financial costs associated with a product liability claim relating to our development or commercialization 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 development and 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 our entrectinib and RXDX-103 programs, we have in-licensed from Lilly the use, development and commercialization rights for our taladegib programs, and we have assumed license agreements from Teva that include rights and obligations relating to our RXDX-105, RXDX-106 and RXDX-108 programs. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of those license agreements and the rights we license under them. Each of the license agreements provides that we are subject to diligence obligations relating to the commercialization and development of product candidates, milestone payments, royalty payments and other obligations. In addition to these license agreements, 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 any of these license agreements, or any future license agreement we may enter on which our business or product candidates are dependent, the licensor 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. The loss of the rights licensed to us under these license agreements, 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 markets 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. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and

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scientific questions and can be uncertain. The standards of patentability and patent eligibility for diagnostic methods, personalized medicine, and biotechnology inventions are evolving and to some extent uncertain, and subject matter that is presently considered to be patentable may not be patentable (and patents directed thereto might not be valid) in the future. 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 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 after obtaining 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 or our licensors are the first to file any patent application related to our product candidates.

Our license agreements relating to our entrectinib, RXDX-103, RXDX-105, RXDX-106, RXDX-108 and taladegib development programs grant us exclusive, worldwide licenses under a portfolio of patents and patent applications directed to the licensed development programs. We own the rights to composition of matter patents and patent applications directed to our RXDX-106 and RXDX-107 programs. The composition of matter patents in the United States expire in 2029 for the issued patent relating to entrectinib, in 2029 for the issued patent relating to RXDX-103, in 2030 for the issued patent relating to RXDX-105, in 2032 for the issued patent relating to RXDX-106, in 2033 for the issued patent relating to RXDX-107, and in 2031 for the issued patent relating to taladegib. There are patent applications pending that cover the composition of matter of certain compounds related to our RXDX-108 program, and we expect that if a United States patent issues from one of these applications it will expire in 2033. 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 any of these product candidates, 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, we may elect to pursue patent protection relating to our product candidates only in 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 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. 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.

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 effectively utilize our intellectual property to protect our products, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially and adversely affect our market position and business and operational results.

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 and maintain any issued patents and pending patent applications covering product candidates we may in-license from third-party owners, there may be instances when the prosecution and maintenance of issued patents and pending patent applications that cover our product candidates remain controlled by our licensors. For instance, NMS has retained certain patent prosecution and maintenance rights under our license agreements relating to our entrectinib and RXDX-103 programs, Daiichi Sankyo holds certain patent prosecution and maintenance rights under our license agreement relating to our RXDX-105 and RXDX-106 programs, Cancer Research Technology holds certain patent prosecution and maintenance rights under our license agreement relating to our RXDX-108 program and Lilly holds certain patent prosecution and maintenance rights under our license agreement relating to our taladegib program. If any of our current or future licensing partners that retain the right to prosecute and maintain patents and pending patent applications covering the product candidates we license from them fail to appropriately prosecute and 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.

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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 October 30, 2015, we had 104 employees, 99 of whom were full-time and 5 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. We expect future growth to impose significant added responsibilities on members of management, particularly as we continue to expand our ongoing entrectinib and other development programs, including the taladegib development programs we in-licensed from Lilly in November 2015 and the four development programs we acquired from Teva in March 2015, including:

- effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals;
- effectively managing our discovery research and preclinical development efforts;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties;
- developing and managing new segments of our internal business, including any sales and marketing functions 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.

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 our October 31, 2013 merger transaction, our November 2013, March 2014, March 2015 and June 2015 common stock offerings, our March 2015 transaction with Teva and our November 2015 transaction with Lilly, and we may experience one or more ownership changes as a result of future transactions in our stock. 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, 2014, we had federal and state net operating loss carryforwards of approximately $33.0 million and $32.1 million, respectively, that could be limited if the merger, the common stock offerings or the Teva and Lilly transactions resulted in an ownership change, or if we experience any other ownership change, which could potentially result in increased future tax liability to us.

Risks Related to Ownership of Our Common Stock

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 October 30, 2015, a total of 29,619,706 shares of our common stock were outstanding. Of those shares, approximately 25,623,365 were freely tradable, without restriction, in the public market. Such shares represented 86.5% 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.

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 of 1933, as amended, or the Securities Act, our effective Registration Statements on Form S-8 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.

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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, which result could 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 October 19, 2015, to register the resale of 3,000,000 shares of our common stock, which represents all of the shares of our common stock issued and sold in our March 2015 transaction with Teva. The resale registration statement permits the resale of these shares at any time without restriction, once the contractual lock-up relating to such shares expires in March 2016. In addition, we entered into a registration rights agreement with Lilly in November 2015 pursuant to which we are required to file a resale registration statement to register the resale of the common stock issued to Lilly in connection the entry into our license agreement. 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, the selling stockholder 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.

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 October 30, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 49.9% 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 are in their best interest.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits
EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1	Agreement and Plan of Reorganization, dated May 7, 2013, by and between Ignyta, Inc. and Actagene Oncology, Inc. (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
2.2	Agreement and Plan of Merger and Reorganization, dated October 31, 2013, by and among Ignyta, Inc. (then known as Infinity Oil & Gas Company), IGAS Acquisition Corp., and Ignyta, Inc. (then known as Ignyta Operating, Inc.) (incorporated by reference to Exhibit 2.2 to the Current Report on Form 8-K filed with the SEC on November 1, 2013).
2.3	Agreement and Plan of Merger, dated June 12, 2014, by and among Ignyta, Inc. (then known as Ignyta Operating, Inc.), and its parent entity Ignyta, Inc. (incorporated by reference to Exhibit 2.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
3.1	Second Amended and Restated Certificate of Incorporation of Ignyta, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
3.2	Amended and Restated Bylaws of Ignyta, Inc. (incorporated by reference to Exhibit 3.2 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
4.1	Form of Common Stock certificate (incorporated by reference to Exhibit 4.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
4.2	Warrant to Purchase Stock, issued to Silicon Valley Bank on June 25, 2012 (incorporated by reference to Exhibit 10.5 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
4.3	Warrant to Purchase Stock, issued to Silicon Valley Bank on February 27, 2013 (incorporated by reference to Exhibit 10.6 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
4.4	Warrant to Purchase Common Stock, dated November 6, 2013, issued to Nerviano Medical Sciences S.r.l. (incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed with the SEC on November 7, 2013).
4.5	Warrant to Purchase Stock, issued to Silicon Valley Bank on September 30, 2014 (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed with the SEC on October 1, 2014).
4.6	Warrant to Purchase Stock, issued to Life Science Loans, LLC on September 30, 2014 (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed with the SEC on October 1, 2014).
4.5	Warrant to Purchase Stock, issued to Silicon Valley Bank on September 30, 2015 (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed with the SEC on September 30, 2015).
4.6	

	Warrant to Purchase Stock, issued to Life Science Loans, LLC on September 30, 2015 (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed with the SEC on September 30, 2015).
10.1	Ignyta, Inc. 2015 Employment Inducement Incentive Award Plan and form of stock option agreement thereunder (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on July 22, 2015).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IGNYTA, INC.

Date: November 9, 2015

By: /s/ Jonathan E. Lim, M.D.
Jonathan E. Lim, M.D.

President and Chief Executive Officer