Ignyta, Inc. Form 10-Q May 10, 2016 Table of Contents

## **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 March 31, 2016

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 (State or other jurisdiction of 45-3174872 (I.R.S. Employer

incorporation or organization)

(Address of principal executive offices)

11111 Flintkote Avenue, San Diego, CA

Identification No.)

92121 (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 May 5, 2016 was 41,645,895.

# IGNYTA, INC.

# FORM 10-Q QUARTERLY REPORT

# FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

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## PART I FINANCIAL INFORMATION

## Item 1. Condensed Financial Statements

## Ignyta, Inc.

#### **Condensed Balance Sheets**

(In thousands, except share data)

	larch 31, 2016 naudited)	Dec	ember 31, 2015
Assets			
Current assets:			
Cash and cash equivalents	\$ 38,347	\$	46,383
Short-term investment securities	75,588		85,420
Prepaid expenses and other current assets	4,326		4,191
Total current assets	118,261		135,994
Long-term investment securities	37,257		40,346
Property and equipment, net	19,373		18,764
Other assets	410		410
Total assets	\$ 175,301	\$	195,514
Liabilities and Stockholders Equity			
Current liabilities:			
Accounts payable	\$ 8,807	\$	3,828
Accrued expenses and other liabilities	11,187		13,860
Note payable, current portion	9,262		6,675
Lease payable, current portion	183		181
Total current liabilities	29,439		24,544
Note payable, net of current portion and discount	20,363		22,821
Lease payable, net of current portion	117		164
Other long-term liabilities	12,910		12,000
Total liabilities	62,829		59,529
Commitments and contingencies			

# 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; 32,366,670 and		
32,339,081 shares issued and outstanding at March 31, 2016 and December 31,		
2105, respectively	3	3
Additional paid-in capital	285,966	284,252
Accumulated deficit	(173,512)	(148,021)
Accumulated other comprehensive loss	15	(249)
Total stockholdors - aguity	112,472	135,985
Total stockholders equity	112,472	155,965
Total liabilities and stockholders equity	\$ 175,301	\$ 195,514

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

# Ignyta, Inc.

## **Condensed Statements of Operations and Comprehensive Loss**

(In thousands, except per share data)

# (Unaudited)

	Three months ended March 31, 2016 2015	
Revenue	\$	\$
Operating expenses:		
Research and development	19,781	20,215
General and administrative	5,227	2,767
Total operating expenses	25,008	22,982
Loss from operations	(25,008)	(22,982)
Other income (expense):		
Interest expense	(790)	(602)
Other income (expense)	306	77
Total other income/ (expense), net	(484)	(525)
Net loss	\$ (25,492)	\$ (23,507)
Net loss per share:	¢ (0, <b>7</b> 0)	
Net loss per common share basic and diluted	\$ (0.79)	\$ (1.15)
Weighted average shares outstanding basic and diluted	32,343	20,466
Comprehensive loss:		
Net loss	\$ (25,492)	\$(23,507)
Unrealized gain on available-for sale investment securities	265	28
Comprehensive loss	\$ (25,227)	\$ (23,479)

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

# Ignyta, Inc.

### **Condensed Statements of Cash Flows**

(In thousands)

# (Unaudited)

	Three months ended March 31, 2016 2015	
Cash flows from operating activities:	2010	2013
Net loss	\$ (25 492)	\$ (23,507)
Adjustments to reconcile net loss to net cash used in operating activities:	$\varphi(23,192)$	$\varphi(23,307)$
In-process research and development charge associated with asset acquisition		11,880
Stock-based compensation	1,702	1,032
Depreciation and amortization of property and equipment	855	372
Accretion and amortization of investment securities	275	353
Amortization of non-cash financing costs	131	67
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	(136)	263
Accounts payable	4,975	869
Accrued expenses and other liabilities	(2,514)	(829)
*		
Net cash used in operating activities	(20,204)	(9,500)
Cash flows from investing activities: Purchases of investment securities Maturities and sales of investment securities	(33,177) 46,087	(19,333) 24,775
Purchases of property and equipment	(713)	(642)
Net cash provided by investing activities	12,197	4,800
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs		41,439
Proceeds from exercise of stock options	15	1
Repayments under capital lease obligations	(44)	(42)
Net cash provided by/ (used in) financing activities	(29)	41,398
Net change in cash and cash equivalents Cash and cash equivalents at beginning of period	(8,036) 46,383	36,698 6,346
Cash and cash equivalents at end of period	\$ 38,347	\$ 43,044

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Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 2,528	\$ 449
Noncash investing and financing activities:		
Capitalized costs associated with leased building	\$ 750	\$
Unrealized gain (loss) on available-for-sale investment securities	\$ 265	\$ 28

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

## 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. Its goal is not just to shrink tumors, but to eradicate residual disease the source of cancer relapse and recurrence in precisely defined patient populations. The Company is pursuing an integrated therapeutic, or Rx, and companion diagnostic, or Dx, strategy for treating cancer patients. Its Rx efforts are focused on discovering, in-licensing or acquiring, then developing and commercializing molecularly targeted therapies 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 therapies 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 financial statements after completion of the merger will include the assets and liabilities 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, 2015.

# Liquidity

The Company had negative cash flow from operations of approximately \$20.2 million during the first quarter of 2016 and, as of March 31, 2016, had an accumulated deficit of approximately \$173.5 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 the Company achieves profitability in the future, it 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 March 31, 2016, the Company had cash, cash equivalents and available-for-sale securities totaling \$151.2 million. In addition, our May 2016 underwritten public offering resulted in aggregate gross proceeds of approximately \$57.5 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately \$53.8 million. While the Company expects that its existing cash, cash equivalents and available-for-sale securities and the funds it

raised in May 2016 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 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. 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, calculating stock-based compensation expense and for determining the value of leased property during the construction period for which the Company has been deemed the accounting owner. Actual results could differ from those estimates.

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

## 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 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, 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.

## **Property and Equipment**

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which generally range from three to seven years, or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the lease term.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. To date, the Company has not experienced any impairment losses on its property and equipment.

The Company establishes assets and corresponding financing liabilities for the construction costs incurred under build-to-suit lease arrangements when it is determined that the Company takes construction risks during the construction period and is deemed the accounting owner of the property during construction. At the end of the construction period, the Company assesses whether the arrangement qualifies for sales recognition under the sale-leaseback accounting guidance in ASC 840.

# 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

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organizations, clinical trial investigational sites, and other 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.

## Income Taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities.

The Company follows the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities based on the technical merits of the position.

## **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.

## Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on available-for-sale investments, are reported net of their related tax effect, to arrive at comprehensive income (loss).

## 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 5.8 million and 4.1 million shares as of March 31, 2016 and 2015, respectively.

## Reclassifications

In April 2015, the FASB issued an accounting standard update which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet, consistent with the treatment of debt discounts. The update did not change the guidance on the recognition and measurement of debt issuance costs. The Company adopted this guidance at the beginning of fiscal 2016. Accordingly, the Company reclassified its previously incurred debt issuance costs to a liability as a direct deduction from the carrying value of its notes payable, consistent with the presentation of its other debt discounts. This accounting treatment was applied retroactively to amounts presented in the Company s balance sheet as of December 31, 2015. These changes had no impact on the Company s previously reported results of operations.

## **Recent Accounting Pronouncements**

In March 2016, the FASB issued amended guidance on employee share-based payment accounting. This update involves several aspects of the accounting for share-based payment transactions, including income tax effects, forfeitures and classifications on the statement of cash flows. This guidance is effective for the fiscal year beginning January 1, 2017, and early adoption is permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

In February 2016, the FASB issued lease guidance, which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing

arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases. A lessee will be required to recognize on the balance sheet the assets and liabilities for leases with lease terms of more than 12 months. The new standard is effective for public companies for the Company s fiscal year beginning January 1, 2019, and early adoption is permitted. The Company is currently evaluating the effect that adopting this standard will have on its financial statements and related disclosures.

In January 2016, the FASB issued new guidance which addresses certain aspects of recognition, measurement, presentation and disclosure of certain assets and liabilities in financial statements. This guidance will be effective in the first quarter of fiscal year 2018 and early adoption is not permitted. The Company is currently evaluating the impact that this guidance will have on its financial statements.

No other new accounting pronouncement issued or effective during the three months ended March 31, 2016 had, or is expected to have, a material impact on the Company s financial statements.

### **3. INVESTMENT SECURITIES**

The following tables summarize the available-for-sale investments held by the Company as of the dates below (*in thousands*):

	As of March 31, 2016					
	Amortized Cost	Gross Unrealized Gains		Unre	ross ealized osses	Fair Market Value
Available-for-sale investment securities:						
Corporate debt securities, short-term	\$ 52,410	\$	25	\$	(18)	\$ 52,417
Corporate debt securities, long-term	17,215		17		(16)	17,216
U.S. government and agency obligations, short-term	23,160		12		(1)	23,171
U.S. government and agency obligations,	23,100		12		(1)	23,171
long-term	20,045		8		(12)	20,041
Total	\$ 112,830	\$	62	\$	(47)	\$ 112,845

	As of December 31, 2015				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value	
Available-for-sale investment securities:					
Commercial paper, short-term	\$ 7,992	\$	\$	\$ 7,992	
Corporate debt securities, short-term	70,505	1	(80)	70,426	
Corporate debt securities, long-term	24,454	2	(100)	24,356	
U.S. government and agency obligations,					
short-term	7,009		(7)	7,002	
U.S. government and agency obligations,					
long-term	16,055		(65)	15,990	

Total	\$126,015	\$	3	\$	(252)	\$125,766
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None of the Company s available-for-sale investment securities held at March 31, 2016 had maturity dates of more 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.

None of the Company s available-for-sale investment securities were in a material unrealized loss position at March 31, 2016. The Company reviewed its investment holdings as of March 31, 2016 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 any of the periods presented.

## 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 cash, cash equivalents and available-for-sale investment securities were as follows (in thousands):

	A	As of Marc	h 31, 201	6	A	s of Decemb	er 31, 20	)15
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	\$38,347	\$	\$	\$ 38,347	\$46,383	\$	\$	\$ 46,383
Short-term investments:								
Commercial paper						7,992		7,992
Corporate debt securities		52,417		52,417		70,426		70,426
U.S. government and agency								
obligations	23,171			23,171	7,002			7,002
Total short-term investments	23,171	52,417		75,588	7,002	78,418		85,420
Long-term investments:								
Corporate debt securities		17,216		17,216		24,356		24,356
U.S. government and agency								
obligations	20,041			20,041	15,990			15,990
Total long-term investments	20,041	17,216		37,257	15,990	24,356		40,346
Total assets at fair value	\$81,559	\$69,633	\$	\$151,192	\$69,375	\$102,774	\$	\$172,149

## **5. BALANCE SHEET DETAILS**

#### **Property and Equipment**

Property and equipment consisted of the following (in thousands):

	As of		As of
	March 31, 2016	Dec	ember 31, 2015
Manufacturing and lab equipment	\$ 7,493	\$	6,941
Leasehold improvements	2,349		2,349

Computer and office equipment	1,306	1,145
Property and equipment at cost	11,148	10,435
Less accumulated depreciation and amortization	(3,525)	(2,671)
Subtotal	7,623	7,764
Construction in process (see below)	11,750	11,000
Property and equipment, net	\$ 19,373	\$ 18,764

Lab equipment includes assets with an acquisition value of \$636,000 (net of accumulated depreciation of \$176,000 and \$144,000 at March 31, 2016 and December 31, 2015, respectively) which were acquired under leases accounted for as capital leases. Depreciation expense for this equipment was approximately \$32,000 during the three months ended March 31, 2016 and 2015, respectively.

### Accrued Expenses and Other Current Liabilities

The following table summarizes major classes of accrued expenses and other current liabilities (in thousands):

	As of March 31, 2016		As of December 31, 2015	
Contracted clinical trial services fees and related costs	\$	4,928	\$	5,766
Research and development services		2,501		1,763
Personnel and related costs		1,181		3,844
Other liabilities		2,577		2,487
Total	\$	11,187	\$	13,860

### **Other Long-Term Liabilities**

Other long-term liabilities consisted of the following (in thousands):

	As of March 31, 2016	As of December 31, 2015	
Leased facility financing obligation (see below)	\$ 11,750	\$ 11,000	
Final loan fee obligation to lender (see note 6)	930	930	
Other	230	70	
Total	\$ 12,910	\$ 12,000	

#### Construction in Process and Leased Facility Financing Obligation

In October 2015, the Company entered into an agreement for the lease of laboratory and office space on a build-to-suit basis for its new headquarters location in San Diego, California. The Company will incur costs to build out the leased space to its specifications, subject to a tenant improvement (TI) allowance from the landlord. The buildings that house the leased space are currently undergoing a significant structural renovation which is expected to be completed during November 2016, at which time the Company will occupy this space. Based on the terms of the lease agreement and applicable accounting rules, the Company was determined to bear substantially all of the construction-related risks during the construction period and was deemed the owner of the building for accounting purposes during the construction in process) and a corresponding leased facility financing obligation reflecting the estimated initial fair value of these buildings at lease inception (of \$10.9 million) and the accumulated build out costs incurred subsequent to the inception of the lease. The fair value measurement of the buildings is categorized within Level 3 of the fair value hierarchy. Upon completion of construction, the Company will occupy the buildings and finalize an assessment of the sale-leaseback criteria to determine whether it will de-recognize both the building assets and the corresponding liability.

## 6. NOTES PAYABLE

The Company has incurred \$31.0 million of indebtedness under its amended and restated loan and security agreement with Silicon Valley Bank (SVB). The Company is required to pay interest on the borrowings under this agreement at a per-annum rate of interest of approximately 8.5% on a monthly basis. The loan principal will be repaid in 36 equal monthly payments commencing in May 2016, such that the loan will be fully paid by April 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 loan agreement.

Future minimum principal payments under this obligation are as follows (in thousands):

	Minimum
Year ending December 31,	Payments
2016 (9 months)	\$ 6,889
2017	10,333
2018	10,333
2019	3,445
Total	\$ 31,000

Under the terms of its loan agreement with SVB, 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, 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 11.5% 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 this 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 certain oncology development programs, including Cephalon s right, title and interest in and to certain intellectual property, compounds, products, contracts, records, data and development supplies related to the Company s RXDX-105 and RXDX-106 programs (the Purchased Assets ), and assumed certain related commitments. As consideration for the Purchased Assets, the Company issued to Cephalon 1,500,000 shares of common stock and assumed certain other third-party obligations. 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. The acquired assets were in various stages of drug development, ranging from preclinical stage to Phase 1 clinical trials, and the development plans were still being formulated and were not complete as of the date of acquisition. As the success of the Company s commercialization of these acquired compounds was uncertain and the assets in question had 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 related to this transaction based on the value of the net assets exchanged for the Teva assets. Under the provisions of the asset purchase agreement, the Company also paid approximately \$0.9 million to Cephalon for drug development supplies, which was included in research and development expenses for the three months ended March 31, 2015.

## 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. The Company s development rights under the license agreement are exclusive for the term of the agreement with respect to entrectinib 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 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

entrectinib 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 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).

## Taladegib

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 an orally

bioavailable, small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase 2 dose in a Phase 1 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 development program for the potential treatment of patients with superficial and nodular basal cell carcinoma. In February 2016, the Company ceased all development activities relating to the topical taladegib program. 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. 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.

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. 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, subject to certain conditions. In addition, a portion of the \$30.0 million in gross proceeds provided to the Company by Lilly in a concurrent private placement of the Company s common stock to Lilly (in November 2015) has been earmarked for development of the product and payment of milestone obligations under the license agreement. When and if commercial sales of Licensed Products begin, the Company will be obligated to pay Lilly a mid-single digit royalty of net sales of Combination Products begin, Lilly will be obligated to pay the Company a mid-single digit royalty of net sales of Combination Products. 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.

## 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.

## 9. COMMITMENTS AND CONTINGENCIES

#### Leases

The Company leases office and laboratory space and certain lab equipment under operating leases that expire through 2026. Certain of the facility leases contain periodic rent increases that result in the Company recording deferred rent over the term of these leases. Future minimum lease payments under the non-cancellable portion of the Company s operating leases totaled \$26.1 million as of March 31, 2016.

The Company has also entered into capital lease arrangements for the purchase of certain lab equipment. Future minimum lease payments under the Company s capital lease obligations totaled \$0.3 million as of March 31, 2016.

#### **Clinical Trial Study Agreement Commitments**

The Company has entered into agreements with several 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 totaled approximately \$39.4 million as of March 31, 2016, of which approximately \$17.6 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.

## **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 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 Offering

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

#### At-The-Market Issuance Sales Agreement

In December 2015, the Company entered into an at-the-market issuance sales agreement (the Sales Agreement ) with Cantor Fitzgerald & Co. ( Cantor ) pursuant to which the Company may issue and sell shares of its common stock from time to time, at the Company s option, through Cantor as its sales agent. The Company is not obligated to make any sales of its common stock under the Sales Agreement, and it may terminate its agreement with Cantor at any time. Any shares sold will be sold pursuant to an effective shelf registration statement on Form S-3. The Company will pay Cantor a commission of 3.0% of the gross proceeds of any such sales. The Company has reserved up to \$33.0 million under its shelf registration statement for shares that may be issued under the Sales Agreement. Through March 31, 2016, the Company has not made any sales of shares in connection with this arrangement.

#### **Restricted Stock**

An aggregate of 3,999 shares associated with restricted stock arrangements were subject to future vesting as of March 31, 2016. 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 restricted shares were repurchased during fiscal 2015 or the first three months of fiscal 2016.

#### **Common Stock Warrants**

Warrants to purchase an aggregate of 59,356 shares of the Company s common stock were outstanding at March 31, 2016. These warrants have a weighted average exercise price of \$6.79 per share and expire at various dates through September 2022.

## **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 equity 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). Options granted under the Company s equity incentive plans are exercisable at various dates and will expire no more than ten years from their date of grant.

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 plans.

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

		Weighted-	Weighted-	<b>A</b>
	Options Outstanding	Average Exercise Price	Average Remaining Term	Aggregate Intrinsic Value
Balance at December 31, 2015	5,250,941	\$ 9.16		
Granted	739,641	\$ 9.65		
Exercised	(27,589)	\$ 0.53		
Forfeited	(555,677)	\$ 11.20		
Balance at March 31, 2016	5,407,316	\$ 9.06	8.5	\$ 2,095,596
Exercisable at March 31, 2016	1,631,125	\$ 6.46	8.5	\$ 2,074,175

As of March 31, 2016, an aggregate of 1,159,688 shares remain available for grant under the Company s equity incentive plans.

## 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* this 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 has 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 options granted during the first quarter of 2016 and 2015 was estimated using the following weighted-average assumptions:

	Fiscal	Fiscal
	2016	2015
Volatility	76%	70%
Expected life of option	6.5 years	6.2 years
Risk free interest rate	1.6%	1.6%
Dividend yield	%	%

The estimated fair value of options granted during the first quarter of 2016 and 2015 was \$6.03 and \$4.68 per share, respectively.

## **Restricted Stock Units**

During the first quarter of 2016, the Company issued 206,880 restricted stock units ( RSUs ) to employees under its 2014 Plan. As of March 31, 2016, a total of 284,880 RSUs were outstanding and subject to future vesting.

#### **Stock-Based Compensation**

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

	Three months ended March 31,		
	2016	2015	
Included in research and development expenses	\$ 816	\$ 468	
Included in general and administrative expenses	886	564	
Total stock-based compensation expense	\$ 1,702	\$1,032	

Unrecognized stock-based compensation expense related to unvested stock-based awards totaled \$21.7 million as of March 31, 2016 and is expected to be recognized over a weighted-average period of 3.2 years.

## **12. SUBSEQUENT EVENT**

In May 2016, the Company completed a public offering of its common stock for the issuance and sale of an aggregate of 9.2 million shares of common stock for net proceeds of approximately \$53.8 million (net of transaction costs of approximately \$3.8 million).

#### 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, 2015, 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, 2015. 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, 2015 and the caption Risk Factors in this Ouarterly 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 are 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 our and our company refer to (i) Parent and us, its consolidated subsidiary, for discussions we, 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 leading precision oncology biotechnology company. Our goal is not just to shrink tumors, but to eradicate 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 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 therapies we develop.

Our current pipeline includes the following compounds:

entrectinib, formerly called RXDX-101, an orally bioavailable, 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 2 clinical study and two Phase 1 clinical studies in molecularly defined adult patient populations for the treatment of solid tumors, and one Phase 1/1b clinical study in pediatric patients with

advanced solid tumor malignancies;

taladegib, an orally bioavailable, small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase 2 dose in a Phase 1 dose escalation trial;

RXDX-105, an orally bioavailable, small molecule multikinase inhibitor with potent activity against such targets as RET and BRAF, that has achieved clinical proof of concept and a recommended Phase 2 dose in an ongoing Phase 1/1b clinical trial; and

RXDX-106, a small molecule, pseudo-irreversible inhibitor of Tyro-3, Axl and Mer, or collectively TAM, and cMET that is in late preclinical development.

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 taladegib under a license agreement with Eli Lilly and Company, or Lilly, in November 2015; and we acquired our RXDX-105 and RXDX-106 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. We are also pursuing our Spark discovery-stage program, directed to an emerging oncology target.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, assembling our core capabilities in genetic and epigenetic based biomarker and drug target discovery, identifying potential product candidates and

developing such candidates. Our product candidate development operations include preparing, managing and conducting preclinical and clinical studies and trials, preparing regulatory submissions relating to those product candidates and establishing and managing relationships with third parties in connection with all of those activities. We expect that in the future our operations may also, if regulatory approval is obtained, include pursuing the commercialization of our product candidates.

#### **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 we 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 CROs 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. 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, and RXDX-106 programs, and drug discovery activities for the development of our Spark program. 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 as those programs progress. 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 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/or 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. For a description of our critical accounting policies, please see Management s Discussion and Analysis of Financial

Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have not been any material changes to our critical accounting policies since December 31, 2015.

### **Recently Issued Accounting Pronouncements**

#### **Recent Accounting Pronouncements**

In March 2016, the FASB issued amended guidance on employee share-based payment accounting. This update involves several aspects of the accounting for share-based payment transactions, including income tax effects, forfeitures and classifications on the statement of cash flows. This guidance is effective for the fiscal year beginning January 1, 2017, and early adoption is permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

In February 2016, the FASB issued lease guidance, which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases. A lessee will be required to recognize on the balance sheet the assets and liabilities for leases with lease terms of more than 12 months. The new standard is effective for public companies for the Company s fiscal year beginning January 1, 2019, and early adoption is permitted. The Company is currently evaluating the effect that adopting this standard will have on its financial statements and related disclosures.

In January 2016, the FASB issued new guidance which addresses certain aspects of recognition, measurement, presentation and disclosure of certain assets and liabilities in financial statements. This guidance will be effective in the first quarter of fiscal year 2018 and early adoption is not permitted. The Company is currently evaluating the impact that this guidance will have on its financial statements.

#### **Results of Operations**

#### Comparison of the Three Months Ended March 31, 2016 and 2015

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015, together with the changes in those items in dollars (*in thousands*) and as a percentage:

		Three months ended March 31,		Percentage
	2016	2015	Change	Change
Revenue	\$	\$	\$	N/A
Operating expenses:				
Research and development	19,781	20,215	(434)	(2%)
General and administrative	5,227	2,767	2,460	89%
Total operating expenses	25,008	22,982	2,026	9%
Loss from operations	(25,008)	(22,982)	(2,026)	(9%)
Other income (expense), net	(484)	(525)	41	8%
Net loss	\$ (25,492)	\$ (23,507)	\$ (1,985)	(8%)

Revenue. We recorded no revenue for the three months ended March 31, 2016 and 2015.

*Research and Development Expense.* Research and development expense decreased during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. During the first quarter of 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, as well as transaction and drug product related costs of \$1.2 million. Excluding these costs, research and development costs would have increased in 2016 as compared to 2015 by \$12.7 million, or 178%, primarily due to an \$8.0 million increase in the development costs associated with our entrectinib, taladegib and other product candidates. Salaries, share-based compensation expense and other personnel-related costs also increased as our research and development expenses during 2016 was attributable to higher travel and consulting costs.

*General and Administrative Expense.* General and administrative, or G&A, expenses increased by approximately \$2.5 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015, an increase of 89%. This increase was driven by higher personnel and share-based compensation costs. Additionally, the Company incurred higher facilities related expenses resulting from the expansion of our leased facilities space, and increases in legal and intellectual property costs, consulting fees and depreciation expenses.

*Other Income (Expense), net.* Other income (expense), net consists principally of interest expense on our loan arrangement with Silicon Valley Bank, or SVB, net of the interest income earned on our portfolio of available-for-sale securities. Other expense, net decreased by approximately \$41,000 or 8% in the first quarter of 2016, reflecting an increase in the return generated by our available-for-sale investment securities (resulting from an increase in our investable funds) which more than offset an increase in interest expense on our obligation to SVB (resulting from the

additional borrowings we made during the third quarter of 2015).

# Liquidity and Capital Resources

### Sources of Liquidity

Since our inception, and through March 31, 2016, we have raised an aggregate of approximately \$293.3 million to fund our operations, of which approximately \$30.0 million was received from our issuance and sale of our common stock to Lilly in November 2015, 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 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 common stock in an underwritten public offering. 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.

*Private Placements*. In November 2015, we issued and sold 1,500,000 shares of common stock to Lilly at a purchase price per share of \$20.00, for aggregate gross and net proceeds of \$30.0 million (the costs associated with this transaction being negligible). 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 November 2013 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.

*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. In addition, our May 2016 underwritten public offering resulted in aggregate gross proceeds of approximately \$57.5 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering resulted in aggregate gross proceeds of approximately \$57.5 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately \$57.8 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. 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.

*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 per-annum interest rate of approximately 8.5% on a monthly basis. The loan principal will be repaid in 36 equal monthly installments, such that the loan will be repaid by April 2019. 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 we pay a prepayment fee 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 11.5% 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 during 2016 and 2015 (in thousands):

	Three months ended, March 31,	
	2016	2015
Net cash used in operating activities	\$ (20,204)	\$ (9,500)
Net cash provided by investing activities	12,197	4,800
Net cash (used in)/ provided by financing activities	(29)	41,398
Net (decrease)/ increase in cash and cash equivalents	\$ (8,036)	\$ 36,698

*Net Cash Used in Operating Activities.* Net cash used in operating activities for 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 \$20.2 million during the first quarter of 2016 compared to approximately \$9.5 million during the same period of 2015. The increase in cash used in operating activities was driven primarily by an increase in activities relating to development of entrectinib, taladegib and our other product candidates and higher salaries, benefits and personnel-related costs resulting from higher headcount to support our expanded clinical and non-clinical development activities.

*Net Cash Provided by Investing Activities.* Net cash provided by investing activities was approximately \$12.2 million during the three months ended March 31, 2016 compared to approximately \$4.8 million provided by such activities during the same period of 2015. The cash provided by investing activities in both periods was primarily due to net redemptions of our available-for-sale securities portfolio, partially offset by the funds used to acquire property and equipment of \$0.7 million during 2016 and \$0.6 million during the same period of 2015.

*Net Cash (Used in)/ Provided by Financing Activities.* Net cash used by financing activities was not significant during the three months ended March 31, 2016, compared to the approximately \$41.4 million provided by financing activities during the same period of 2015. There was no significant financing activity during 2016. Cash provided by financing activities during 2015 was primarily the result of the funds raised through the sale of our common stock.

# 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 and RXDX-106, and as we continue the research and development of our Spark program. 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.

As of March 31, 2016, we had approximately \$151.2 million in cash, cash equivalents and available-for-sale securities. In addition, our May 2016 underwritten public offering resulted in aggregate gross proceeds of approximately \$57.5 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately \$53.8 million. We expect that our existing cash, cash equivalents and available-for-sale securities and the funds we raised in May 2016 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, limit, reduce or terminate 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.

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. continu should or would, or the negative of these terms or other comparable anticipate, intend, seek, expect, plan, 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 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 current product candidates, and any future 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, potentially with partners, to validate, develop and obtain regulatory approval of companion diagnostics for our product candidates; our ability to protect our intellectual property rights, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; our ability to develop and/or obtain 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 *Interest Rate Fluctuation Risk*

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in commercial paper and debt instruments of financial institutions, corporations, US government-sponsored agencies and the US Treasury. The primary

objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. Because of the short-term maturities of our cash equivalents and marketable investment securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our marketable investment securities. If a 10% change in interest rates were to have occurred on March 31, 2016, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We have a loan arrangement with SVB under which we have borrowed \$31.0 million, and which accrues interest at approximately 8.5%. The interest rate is fixed during the loan term and therefore does not subject us to interest rate fluctuation risk.

#### Foreign Currency Exchange Risk

We contract with CROs and investigational sites in several foreign countries, including countries in Eastern and Western Europe and the Asian Pacific. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. To date we have not incurred any material adverse effects from foreign currency changes on these contracts.

# Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during either fiscal 2016 or 2015.

# 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.

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 March 31, 2016 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.

# 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, 2015 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. You should carefully consider the risk factors discussed in our Annual Report on Form 10-K. Set for the risk 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, 2015 was \$92.5 million, and our net loss for the quarter ended March 31, 2016 was \$25.5 million. As of March 31, 2016, we had an accumulated deficit of \$173.5 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 public offering of common stock that was consummated in May 2016, our other 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 the taladegib development program we acquired from Eli Lilly and Company, or Lilly, in November 2015 and the RXDX-105 and RXDX-106 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 2 clinical trial of oral entrectinib in adult patients with advanced or metastatic cancer detected to be positive for relevant molecular alterations. We are conducting and 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.

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.

# **Risks Related to Our Dependence on Third Parties**

# We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws). We can face serious consequences for violations.

Among other matters, Trade Laws prohibit companies and their employees, agents, contract research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

# **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 and RXDX-106 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 breadth, validity and enforceability of patents in the biotechnology and pharmaceutical field involves

complex legal and 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. It is possible that we will fail to identify patentable aspects of our discovery and development activities before it is too late to obtain patent protection. There may be prior art of which we are not aware that may affect the breadth, validity or enforceability of our patents and patent applications. There also may be prior art of which we are aware, but which we do not believe affects the breadth, validity or enforceability of our patents, which may, nonetheless, ultimately be found to affect the breadth, validity or enforceability of our patents. 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 inventorship, ownership, breadth, validity, or enforceability of any issued patents we own or license or any patent applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable or the patent applications failing to issue as patents. 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. We may be required to disclaim part or all of the subject matter and/or term of certain patents or all of the subject matter and/or patent term of certain of our patents and patent applications. If the inventorship, ownership, breadth, validity, or enforceability of the patents we own or license is threatened, our ability to effectively 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 likely be reduced. Since patent applications filed 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 such applications that we or our licensors are the first to file any patent application related to our product candidates.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and prospects.

Our license agreements relating to our entrectinib, RXDX-103, RXDX-105, RXDX-106 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-105, in 2032 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. 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.

Inventions, and the intellectual property rights covering them, that are discovered under research, material transfer or other such collaboration agreements may become solely owned by us in some cases, jointly owned by us and the other party to such agreements in some cases, and may become the exclusive property of other party to such agreements in other cases. Under some circumstances, it may be difficult to determine which party owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators may have contractual rights that permit them to use our proprietary compounds for specific studies, and publish our data and other proprietary information, subject to our prior review. Unauthorized uses of our proprietary compounds by such research collaborators, and publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may limit or foreclose our ability to obtain patent protection for our product candidates or protect our proprietary information, which could materially harm our business, prospects, financial condition and results of operations.

In addition, issued patents and pending patent applications require regular maintenance and payment of taxes, fees and/or annuities in several stages over the lifetime of the patents and patent applications. We employ an outside firm and rely on our outside counsel to

pay these fees when they are due. We, the outside firm or our outside counsel could inadvertently abandon a patent or patent application due to non-payment of such taxes, fees and/or annuities, or as a result of a failure to comply with filing deadlines or other requirements of the prosecution process, resulting in the loss of protection of certain intellectual property rights in a certain country. Alternatively, we, our collaborators, or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated, or if reinstated, may result in a reduction of patent term. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents lapsed, void, or unenforceable, prematurely terminating pending applications, or reducing patent term.

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, inventions 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. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, if our competitors independently develop equivalent knowledge, methods or know-how, it will be more difficult or impossible for us to enforce our rights and our business could be materially harmed. 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, and Lilly holds certain patent prosecution and maintenance rights under our license agreement relating to programs. 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.

# 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 April 30, 2016, we had 123 employees, 117 of whom were full-time and six 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 program we in-licensed from Lilly in November 2015 and the RXDX-105 and RXDX-106 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 may 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 and 383 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, June 2015 and May 2016 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. We have not performed, nor do we have any current plan to perform, a formal study of such potential limitations on the use of our net operating loss carryforwards and other tax assets. 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, 2015, we believe we had federal and state net operating loss carryforwards of approximately \$92.3 million and \$91.7 million, respectively. These net operating loss carryforwards 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. In addition, we are reporting an uncertain tax position in respect of approximately \$23.9 million of our California state net operating loss carryforward, which carryforward would be disallowed unless a recent California Supreme Court decision on apportionment is overturned.

#### **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 May 5, 2016, a total of 41,645,895 shares of our common stock were outstanding. Of those shares, approximately 37,369,466 were freely tradable, without restriction, in the public market. Such shares represented approximately 90% 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.

# The resale of shares covered by our resale registration statements 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 registration statements with the SEC to register the resale of all of the 3,000,000 shares of our common stock issued and sold to Teva in March 2015, and all of the 2,713,000 shares of our common stock issued and sold to Lilly in November 2015. Both of these registration statements have been declared effective by the SEC. The resale registration statements permit the resale of these shares at any time without restriction, with respect to the shares held by Teva, and once the contractual lock-up relating to such shares expires in May 2016, with respect to the shares held by Lilly. 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 statements, the selling stockholders named in such registration statements may continue to offer shares covered by the resale registration statements 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 statements 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 May 5, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 46% 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.

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 Company s 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).
4.7	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).
4.8	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\* Amended and Restated Ignyta, Inc. Severance and Change in Control Severance Plan dated January 7, 2016
- 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.

# 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: May 10, 2016

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

President and Chief Executive Officer