

Ignyta, Inc.  
Form 10-Q  
August 12, 2014  
**Table of Contents**

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended June 30, 2014**

**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**  
**incorporation or organization)**

**45-3174872**  
**(I.R.S. Employer**  
**Identification No.)**

**11095 Flintkote Avenue, Suite D, San Diego, CA**  
**(Address of principal executive offices)**  
**(858) 255-5959**

**92121**  
**(Zip Code)**

**(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.  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).  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

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

The number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, as of August 1, 2014 was 19,579,588.

**Table of Contents**

**IGNYTA, INC.**  
**FORM 10-Q QUARTERLY REPORT**  
**FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2014**  
**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	1
<b><u>Item 1. Unaudited Financial Statements</u></b>	1
<u>Condensed Balance Sheets at June 30, 2014 (unaudited) and December 31, 2013 (audited)</u>	1
<u>Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2014 and 2013, and for the period from August 29, 2011 (Inception) through June 30, 2014 (unaudited)</u>	2
<u>Condensed Statements of Stockholders' Equity from August 29, 2011 (Inception) through June 30, 2014 (unaudited)</u>	3
<u>Condensed Statements of Cash Flows for the six months ended June 30, 2014 and 2013, and for the period from August 29, 2011 (Inception) through June 30, 2014 (unaudited)</u>	4
<u>Notes to Condensed Financial Statements (unaudited)</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	24
<b><u>PART II OTHER INFORMATION</u></b>	24
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	36
<u>Item 4. Mine Safety Disclosures</u>	36
<u>Item 5. Other Information</u>	36
<u>Item 6. Exhibits</u>	37
<b><u>SIGNATURES</u></b>	38

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Ignyta, Inc.****(A Development Stage Company)****Condensed Balance Sheets**

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
	(Unaudited)	(Audited)
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 34,564,871	\$ 51,803,716
Short term investments	40,839,020	
Prepaid expenses and other current assets	848,285	671,373
Total current assets	76,252,176	52,475,089
<b>Fixed Assets - Net</b>		
Long term investments	19,742,553	
Other Assets	63,045	13,045
	\$ 98,587,003	\$ 53,318,840
<b>Liabilities and Stockholders Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,987,766	\$ 811,600
Accrued expenses and other liabilities	1,602,916	590,235
Note payable, current portion	1,525,442	
Warrant liability	181,800	129,400
Total current liabilities	5,297,924	1,531,235
Note payable, net of current portion and discount	7,572,021	8,950,000
Other liabilities	1,050,000	1,050,000
Total liabilities	13,919,945	11,531,235
<b>Commitments and Contingencies (Note 11)</b>		
<b>Stockholders Equity</b>		
Preferred Stock, \$.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding		
Common Stock, \$.0001 par value; 150,000,000 shares authorized 19,579,588 and 13,934,876 shares issued and outstanding, respectively	1,958	1,393
Additional paid-in capital	109,761,792	57,359,152

Edgar Filing: Ignyta, Inc. - Form 10-Q

Deficit accumulated during the development stage	(25,102,254)	(15,572,940)
Accumulated other comprehensive income	5,562	
Total stockholders' equity	84,667,058	41,787,605
	\$ 98,587,003	\$ 53,318,840

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

Table of Contents**Ignyta, Inc.****(A Development Stage Company)****Unaudited Condensed Statements of Operations and Comprehensive Loss**

	<b>Three Months Ended June 30, 2014</b>	<b>Three Months Ended June 30, 2013</b>	<b>Six Months Ended June 30, 2014</b>	<b>Six Months Ended June 30, 2013</b>	<b>Period from August 29, 2011 (Inception) through June 30, 2014</b>
<b>Revenue</b>	\$ 150,000	\$	\$ 150,000	\$	\$ 150,000
<b>Expenses</b>					
Research and development	3,575,787	584,920	5,758,367	1,220,664	16,677,146
General and administrative	2,038,721	527,365	3,794,965	903,696	8,113,362
<b>Loss from Operations</b>	<b>(5,464,508)</b>	<b>(1,112,285)</b>	<b>(9,403,332)</b>	<b>(2,124,360)</b>	<b>(24,640,508)</b>
<b>Other Income (Expense)</b>					
Other income (expense)	(25,637)	(7,100)	(52,658)	5,700	(158,610)
Interest income (expense)	67,622	(22,017)	(68,020)	(35,475)	(294,428)
<b>Total Other Income (Expense)</b>	<b>41,985</b>	<b>(29,117)</b>	<b>(120,678)</b>	<b>(29,775)</b>	<b>(453,038)</b>
<b>Loss Before Income Taxes</b>	<b>(5,422,523)</b>	<b>(1,141,402)</b>	<b>(9,524,010)</b>	<b>(2,154,135)</b>	<b>(25,093,546)</b>
Income tax provision			5,304	2,095	8,708
<b>Net Loss</b>	<b>\$ (5,422,523)</b>	<b>\$ (1,141,402)</b>	<b>\$ (9,529,314)</b>	<b>\$ (2,156,230)</b>	<b>\$ (25,102,254)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.28)</b>	<b>\$ (0.84)</b>	<b>\$ (0.56)</b>	<b>\$ (2.13)</b>	<b>\$</b>
<b>Weighted average shares</b>	<b>19,578,733</b>	<b>1,366,705</b>	<b>17,054,031</b>	<b>1,011,990</b>	
<b>Comprehensive Loss</b>					
Net loss	\$ (5,422,523)	\$ (1,141,402)	\$ (9,529,314)	\$ (2,156,230)	\$ (25,102,254)
Unrealized gain on available for sale securities	36,678		5,562		5,562
<b>Comprehensive loss</b>	<b>\$ (5,385,845)</b>	<b>\$ (1,141,402)</b>	<b>\$ (9,523,752)</b>	<b>\$ (2,156,230)</b>	<b>\$ (25,096,692)</b>

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

**Table of Contents**

**Ignyta, Inc.**

**(A Development Stage Company)**

**Condensed Statements of Stockholders Equity**

	Convertible Preferred Stock Series A		Convertible Preferred Stock Series B		Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance at August 29, 2011</b>		\$		\$		\$	\$	\$	\$	\$
Balance of restricted stock					666,668	66	1,934			2,000
Balance of Series A Preferred Stock net of offering costs	416,667	42					220,736			220,736
Stock-based compensation expense							781			781
Net loss								(79,445)		(79,445)
<b>Balance at December 31, 2011 (audited)</b>	416,667	42			666,668	66	223,451	(79,445)		144,112
Purchase of common stock					(13,334)	(1)	(39)			(13,774)
Balance of Series A Preferred Stock net of offering costs	416,667	42					249,100			249,100
Balance of Series B Preferred Stock net of offering costs			1,835,000	183			5,423,848			5,424,031

uring costs									
ck-based compensation ense							23,373		23,373
loss								(1,279,852)	(1,279,852)
<b>Balance at December 31, 2022 (Audited)</b>	833,334	84	1,835,000	183	653,334	65	5,919,733	(1,359,297)	4,560,773
Balance of Common Stock									
Retained Earnings									
to stock holders									
exercised					12,290	1	2,999		3,000
Balance of Restricted Common Stock due to Share Repurchase									
Program					1,583,336	158	5,542		5,776
Conversion of Preferred Common Stock due to Reverse Merger	(833,334)	(84)	(1,835,000)	(183)	2,675,678	267			
Balance of Common Stock net of Share Repurchase Program									
47,687 in Share Repurchase Program					9,010,238	902	51,012,839		51,013,727
uring costs									
ck-based compensation ense							370,439		370,439
Balance of Grant Loss							47,600		47,600
Loss								(14,213,643)	(14,213,643)
<b>Balance at December 31, 2023 (Audited)</b>					13,934,876	1,393	57,359,152	(15,572,940)	41,787,601
Balance of Common Stock									
to stock holders									
exercised					12,962	2	5,470		5,474
Purchase of Restricted Common Stock					(400,000)	(40)	(1,400)		(1,440)
Balance of Common Stock					6,031,750	603	51,581,240		51,581,803



Balance of Common Stock net of 608,670 in incurred costs								
Stock-based compensation expense					817,330			817,330
Realized loss on securities available for sale							5,562	5,562
					(9,529,314)			(9,529,314)
<b>Balance at September 30, 2014 (audited)</b>	\$	\$	19,579,588	\$ 1,958	\$ 109,761,792	\$ (25,102,254)	\$ 5,562	\$ 84,667,000

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

Table of Contents**Ignyta, Inc.****(A Development Stage Company)****Unaudited Condensed Statements of Cash Flows**

	<b>Six Months Ended June 30, 2014</b>	<b>Six Months Ended June 30, 2013</b>	<b>Period from August 29, 2011 (Inception) through June 30, 2014</b>
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (9,529,314)	\$ (2,156,230)	\$ (25,102,254)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	111,708	48,076	237,980
Loss on sale of assets	1,437		30,788
Stock-based compensation	817,330	42,226	1,211,923
Non-cash interest expense		12,700	110,756
Change in fair value of warrant liabilities	52,400	(5,700)	129,000
Accretion and amortization on debt securities	285,540		285,540
Warrant issued for license agreement			47,600
Amortization of debt discount	147,463	5,494	200,263
Increase (decrease) in cash resulting from changes in:			
Prepaid expenses and other current assets	(226,912)	(102,349)	(1,022,086)
Accounts payable trade	1,176,166	25,098	1,987,766
Accrued expenses and other liabilities	912,681	74,694	1,502,916
<b>Net cash used in operating activities</b>	<b>(6,251,501)</b>	<b>(2,055,991)</b>	<b>(20,379,808)</b>
<b>Cash Flows From Investing Activities</b>			
Purchases of investments	(62,332,770)		(62,332,770)
Sales of investments	1,471,219		1,471,219
Purchases of fixed assets	(1,711,668)	(246,585)	(2,707,997)
Proceeds received from sale of assets			10,000
<b>Net cash used by investing activities</b>	<b>(62,573,219)</b>	<b>(246,585)</b>	<b>(63,559,548)</b>
<b>Cash Flows From Financing Activities</b>			
Net proceeds from issuance of Common Stock	51,581,843		102,595,584
Proceeds from issuance of notes payable		500,000	11,500,000
Payments on notes payable			(1,500,000)
Net proceeds from issuance of Restricted Stock		5,700	7,700
Net proceeds from issuance of Preferred Stock			5,893,951
Net proceeds from stock options exercised	5,472		8,472
Repurchase of Common Stock	(1,440)		(1,480)

<b>Net cash provided by financing activities</b>	51,585,875	505,700	118,504,227
<b>Net Change in Cash and Cash Equivalents</b>	(17,238,845)	(1,796,876)	34,564,871
<b>Cash and Cash Equivalents at Beginning of Period</b>	51,803,716	5,032,307	
<b>Cash and Cash Equivalents at End of Period</b>	\$ 34,564,871	\$ 3,235,431	\$ 34,564,871
<b>Supplemental Disclosures of Cash Flow Information:</b>			
Interest	\$ 292,178	\$ 17,282	\$ 353,634
Income taxes	\$ 5,304	\$ 2,095	\$ 8,708
<b>Noncash investing and Financing Activities:</b>			
Warrants issued with debt financing recorded as debt discount	\$	\$ 12,100	\$ 52,800
Leasehold improvement paid by landlord	\$ 100,000	\$	\$ 100,000
Unrealized gain on available for sale securities	\$ 5,562	\$	\$ 5,562

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

---

**Table of Contents**

**Notes to Financial Statements**

**1. Summary of Significant Accounting Policies**

*Nature of operations*

A summary of the Company's significant accounting policies consistently applied in the preparation of the accompanying financial statements follows.

**Ignyta, Inc.** ( Ignyta ) was founded in 2011 and is incorporated in the state of Delaware. On June 12, 2014, Ignyta, Inc. merged with and into Ignyta Operating, Inc. with Ignyta Operating, Inc. surviving the merger and changing its name to Ignyta, Inc.

On October 31, 2013, Ignyta merged with and into IGAS Acquisition Corp., a wholly-owned subsidiary of Ignyta, Inc., a Nevada corporation previously named Infinity Oil & Gas Company (see Note 2). As used in these financial statements, unless the context indicates or otherwise requires, the Company, we, us, and our refer to Ignyta.

In May 2013, the Company acquired Actagene Oncology, Inc. ( Actagene ), a San Diego based privately held biotechnology company developing precision medicines for high unmet need cancer indications, based on cancer genome mining and sequencing. With the acquisition, the Company changed its business strategy from a prior focus on molecular diagnostics for autoimmune disease to an integrated drug and diagnostic, or Rx/Dx, focus on drug and biomarker discovery and development for oncology (see Note 3).

The Company is a precision medicine biotechnology company dedicated to discovering or acquiring, then developing and commercializing, precisely targeted new drugs for cancer patients whose tumors harbor specific molecular alterations. The Company pursues an Rx/Dx strategy, where it aims to pair each of its innovative drugs with biomarker-based companion diagnostics, developed by the Company or by third parties with which it may partner, that are designed to identify the patients that are most likely to benefit from the use of the drugs that the Company may develop.

*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 Securities and Exchange Commission ( 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, 2013, from which the balance sheet information herein was derived.

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

*Development stage*

As of June 30, 2014, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

**Table of Contents**

*Liquidity*

As of June 30, 2014, the Company had an accumulated deficit of approximately \$25,102,000. The Company also had negative cash flow from operations of approximately \$6,252,000 during the six months ended June 30, 2014.

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.

We are currently focused primarily on the development of our RXDX-101, Spark-1, Spark-2 and Spark-3 programs, and we intend to devote resources to our newly-licensed RXDX-103 and RXDX-104 programs. We believe such activities will result in our continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of our products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, 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. The Company intends to cover its future operating expenses through cash on hand and through additional financing from existing and prospective investors. We cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

While we expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements for at least the next twelve months, having insufficient funds may require us to delay, reduce, or eliminate some or all of our development programs. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise 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 our ability to operate our business.

*Use of estimates*

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

*Cash and cash equivalents*

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

*Investments*

Investments consist of corporate notes and bonds and commercial paper. The Company classifies investments as available-for-sale at the time of purchase. All investments are recorded at estimated fair value. Unrealized gains and losses for available-for-sale securities are included in accumulated other comprehensive income,

a component of stockholders' equity. The Company evaluates its investments as of each balance sheet date to assess whether those with unrealized loss positions are other-than-temporarily impaired. Impairments are considered to be other-than-temporary if they are related to deterioration in credit risk or if it is likely that 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 and are reported in other income (expense), net in the Statements of Operations. No other-than-temporary impairment charges have been recognized since inception.

*Fixed assets*

Fixed assets are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, generally 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.

*Impairment of long-lived assets*

In accordance with authoritative guidance related to impairment or disposal of long-lived assets, management reviews the Company's long-lived asset groups for impairment whenever events indicate that their book value may not be recoverable. When management determines that one or more impairment indicators are present for an asset group, it compares the book value of the asset group to net future undiscounted cash flows that the asset group is expected to generate. If the book value of the asset group is greater than the net future undiscounted cash flows that the asset group is expected to generate, it compares the fair value to the book value of the asset group. If the fair value is less than the book value, it recognizes an impairment loss. The impairment loss would be the excess of the book value of the asset group over its fair value. To date, the Company has not experienced any impairment losses on its long-lived assets used in operations.

*Stock-based compensation*

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718, *Compensation - Stock Compensation*, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

*Fair value of financial instruments*

The Company's financial instruments consist of cash and cash equivalents, investments, prepaid expenses and other assets, accounts payable, accrued expenses, and notes payable. 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 significant judgment and therefore cannot be determined with precision. As of June 30, 2014 and December 31, 2013, the book values are generally considered to be representative of their respective fair values.

because of the short-term nature of those instruments.

*Derivative liabilities*

The Company accounts for its warrants as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on the Company's balance sheet at their fair value on the date of issuance and revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future events, expected volatility, expected life, yield, and risk free interest rate.

*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.

*Earnings per share*

( *EPS* )

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 EPS calculation 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.

*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 investments, are reported net of their related tax effect, to arrive at comprehensive income (loss).

*Research and development  
costs*

The Company is actively engaged in new product development efforts for which related costs are expensed as incurred.



**Table of Contents***Fair value measurement*

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 following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

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.

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.

The following table presents the Company's fair value hierarchy for assets and liabilities measured at fair value on a recurring basis as of June 30, 2014 and December 31, 2013 (in thousands):

	June 30, 2014				December 31, 2013			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Cash and cash equivalents	\$ 34,565	\$	\$	\$ 34,565	\$ 51,804	\$	\$	\$ 51,804
<b>Short-term investments:</b>								
Corporate debt securities								
Financial		27,532		27,532				
Industrial		6,265		6,265				
Utility		1,451		1,451				
Commercial paper								
Financial		5,591		5,591				
Industrial								
<b>Total short-term investments</b>	<b>\$</b>	<b>\$ 40,839</b>	<b>\$</b>	<b>\$ 40,839</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Long-term investments:</b>								

Corporate debt securities								
Financial		12,778		12,778				
Industrial		6,965		6,965				
Utility								
Total long-term investments	\$	\$ 19,743	\$	19,743	\$	\$	\$	\$
Total assets measured at fair value	\$ 34,565	\$ 60,582	\$	\$ 95,147	\$ 51,804	\$	\$	\$ 51,804
<b>Liabilities:</b>								
Warrant liability			182	182			129	129
Total liabilities measured at fair value	\$	\$	\$ 182	\$ 182	\$	\$	\$ 129	\$ 129

The Company holds available-for-sale securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its debt 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 Company used Level 3 inputs for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a binomial option pricing model based on various assumptions (see Note 9). The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to fair value of derivative liabilities.

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the six months ended June 30, 2014:

<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3)</b>	
	<b>Warrant Derivative Liability</b>
Beginning Balance at December 31, 2011	\$
Issuances	24,500
Ending Balance at December 31, 2012	\$ 24,500
Issuances	28,300
Adjustments to estimated fair value	76,600
Ending Balance at December 31, 2013	\$ 129,400
Adjustments to estimated fair value	52,400
Ending Balance at June 30, 2014	\$ 181,800

## 2. Reverse Merger

For purposes of the below descriptions in this Note 2, the PIPE financings and the 2011 Plan (each as defined below), all references to Ignyta shall refer to Ignyta, Inc., a Nevada corporation whose name was changed from Infinity Oil & Gas Company on October 31, 2013 in connection with the closing of the Merger; and all references to Merger Sub shall refer to IGAS Acquisition Corp., a Delaware corporation and a wholly owned subsidiary of Ignyta.

On October 31, 2013, Ignyta, Merger Sub, and the Company entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement). The Merger Agreement provided for the merger of Merger Sub with and into the Company (the Merger), with the Company surviving the transaction as a wholly owned subsidiary of Ignyta. The Merger closed on October 31, 2013 concurrently with the execution and delivery of the Merger Agreement.

Also on October 31, 2013, prior to the execution and delivery of the Merger Agreement and the concurrent closing of the Merger, (i) the holders of all series of outstanding preferred stock of the Company, consisting of Series A Preferred Stock and Series B Preferred Stock, voluntarily converted such shares into shares of the Company's common stock in accordance with the certificate of incorporation of the Company and at the then-effective conversion rates therefor, which were one-to-one in all cases, and (ii) the Company amended its certificate of incorporation to change its name to Ignyta Operating, Inc. and to effect a three-to-one reverse stock split of its capital stock, resulting in 4,916,469 outstanding shares of the Company's common stock, outstanding warrants to acquire up to an aggregate of 25,001 shares of the Company's common stock, and outstanding options granted under the Company's 2011 Stock Incentive Plan (as amended and restated, the 2011 Plan) to purchase up to an aggregate of 358,986 shares of the Company's common stock.

At the closing of the Merger and pursuant to the terms of the Merger Agreement, Ignyta issued an aggregate of 4,916,469 shares of its common stock to the former stockholders of the Company in exchange for all of the outstanding shares of the Company's capital stock. That number of shares was negotiated and agreed to by Ignyta and the Company prior to entering into the Merger Agreement. As of immediately following the closing of the Merger, the Company became a wholly-owned subsidiary of Ignyta, and the former stockholders of the Company collectively owned approximately 99.85% of the outstanding shares of Ignyta's common stock. In addition, pursuant to the terms of the Merger Agreement, as of the closing of the Merger Ignyta assumed (i) the 2011 Plan, under which an aggregate of 342,209 shares were reserved for issuance pursuant to future equity grants, (ii) the obligation to issue up to an aggregate of 358,986 shares of its common stock upon the exercise of all options granted under the 2011 Plan that were outstanding as of immediately prior to the closing of the Merger, and (iii) the obligation to issue up to an aggregate of 25,001 shares of its common stock upon the exercise of two warrants previously issued by the Company and outstanding as of immediately prior to the closing of the Merger.

On June 12, 2014, Ignyta merged with and into the Company, with the Company surviving the merger and changing its name to Ignyta, Inc. (the "Reincorporation Merger"). At the closing of the Reincorporation Merger, (i) each outstanding share of Ignyta's common stock was converted into one share of common stock of the Company, (ii) each outstanding option to purchase, or other equity award relating to, Ignyta's common stock was deemed to constitute an option to purchase, or other equity award relating to, common stock of the Company with no change in the exercise price or other terms or provisions of the award, (iii) the shares of Ignyta's common stock that remained available for issuance under the 2011 Plan and the 2014 Incentive Award Plan (the "2014 Plan," and, together with the 2011 Plan, the "Ignyta Plans"), were deemed to relate to shares of the Company's common stock, and (iv) each outstanding warrant to purchase Ignyta's common stock was deemed to constitute a warrant to purchase an equal number of shares of common stock of the Company with no change in the exercise price or other terms or provisions of the warrant.

**Table of Contents**

- 3. Actagene Merger** In May 2013, the Company entered into an Agreement and Plan of Reorganization with Actagene. In accordance with the agreement, Actagene was merged into the Company and the separate corporate existence of Actagene ceased, with the Company continuing as the surviving corporation. On May 20, 2013, the merger was effected and the Company issued 1,583,336 shares of restricted common stock in exchange for the cancellation of all of the outstanding shares of Actagene.

The merger was accounted for as a combination of entities under common control. The majority stockholder of the Company was also the majority stockholder of Actagene, with approximately 60% of the voting power in each entity. Additionally, representatives of the majority stockholder controlled the day to day operations and were on the board of directors of each entity.

- 4. Investments** The Company determines the appropriate designation of investments at the time of purchase and reevaluates such designation as of each balance sheet date. As of June 30, 2014, the Company's short-term investments have maturity dates of less than one year from the balance sheet date. The Company's 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.

The following table summarizes investments by security type as of June 30, 2014:

	June 30, 2014 (in thousands)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<b>Available-for-sale securities:</b>				
Corporate debt securities, short-term	\$ 40,840	\$	\$ (1)	\$ 40,839
Corporate debt securities, long-term	\$ 19,736	\$ 7	\$	\$ 19,743
<b>Total</b>	<b>\$ 60,576</b>	<b>\$ 7</b>	<b>\$ (1)</b>	<b>\$ 60,582</b>

- 5. Fixed Assets** Fixed assets consisted of the following:

Edgar Filing: Ignyta, Inc. - Form 10-Q

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Manufacturing and lab equipment	<b>\$ 2,337,895</b>	\$ 775,872
Office furniture	<b>115,461</b>	59,095
Computers and equipment	<b>168,375</b>	110,857
Leasehold Improvements	<b>133,067</b>	
	<b>2,754,798</b>	945,824
Less accumulated depreciation and amortization	<b>(225,569)</b>	(115,118)
	<b>\$ 2,529,229</b>	\$ 830,706

Depreciation expense for three months ended June 30, 2014 and 2013 was \$63,108 and \$27,514, respectively, and for the six months ended June 30, 2014 and 2013 and for the period from inception (August 29, 2011) through June 30, 2014 was \$111,708, \$48,077, and \$237,980, respectively.

**Table of Contents****6. Notes Payable**

On December 31, 2013 the Company entered into an amended and restated loan and security agreement (the *New Loan Agreement* ) with a financial institution. The *New Loan Agreement* replaced the prior loan and security agreement (the *Loan Agreement* ) which was first entered into in June 2012 and amended in February 2013. The maximum borrowing amount under the *New Loan Agreement* was increased from \$1,500,000 to \$10,000,000. All principal and interest due on the prior *Loan Agreement* was paid in full and the Company was advanced the net proceeds on December 31, 2013. Payments of principal and interest are due on the *New Loan Agreement* on a fully amortized basis of 36 months in equal monthly installments, commencing after a twelve-month period of interest only payments, such that all amounts owed under the *New Loan Agreement* will mature on December 1, 2017. Upon such maturity date, the Company will also owe to the lender a final payment of \$1,050,000, equal to 10.50% of the full principal amount under the *New Loan Agreement*. The final payment of \$1,050,000 is presented as a debt discount on the related debt to be amortized to interest expense. Interest on the \$10,000,000 note was fixed on the date of funding at 6.92%. The loan is collateralized by substantially all of the assets of the Company, other than its intellectual property.

As additional consideration for the cost and risk associated with the *Loan Agreement*, the Company issued to the lender a warrant to purchase up to 8,334 shares of Series B Preferred Stock in June 2012, and an additional warrant to purchase up to a number of shares of Series B Preferred Stock equal to 5% of the amount loaned under the *Loan Agreement* on February 27, 2013 and thereafter, subject to adjustment as set forth in the warrant, including without limitation for stock combinations and splits. As a result, following the final advance under the *Loan Agreement* in July 2013, the warrant became exercisable for 16,667 shares of the Company's Series B Preferred Stock. The warrants issued in 2013 and 2012 were recorded at fair values of \$28,300 and \$24,500, respectively, and were presented as a debt discount on the related debt to be amortized to interest expense over the term of the *Loan Agreement* (See Note 9). Both warrants were assumed by Ignyta in connection with the Merger (see Note 2). No new warrants were issued in conjunction with the *New Loan Agreement*, and as a result of the payoff of the original loan, the debt discount was written off on December 31, 2013.

Interest expense due to amortization of the debt discount for the three months ended June 30, 2014 and 2013 was \$73,102 and \$3,367, respectively, and for the six months ended June 30, 2014 and 2013 and for the period from inception (August 29, 2011) through June 30, 2014 was \$147,463, \$5,494 and \$200,263, respectively.

Future minimum principal payments on notes payable are as follows:

<i>Twelve Months ending June 30,</i>	
2015	\$ 1,525,442
2016	3,212,403
2017	3,446,423
2018	1,815,732

Total	\$ 10,000,000
-------	---------------

## 7. Stockholders Equity

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 our 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.

On March 19, 2014, the Company completed a secondary public stock offering providing for the issuance and sale to investors of an aggregate of 6,031,750 shares of its common stock at a purchase price of nine dollars and fifteen cents (\$9.15) per share for gross proceeds of approximately \$55.2 million.

On November 29, 2013, the Company completed a PIPE financing with 195 accredited investors, providing for the issuance and sale to such investors of an aggregate of 1,270,096 shares of its common stock at a purchase price of six dollars (\$6.00) per share, for gross proceeds of approximately \$7.6 million.



**Table of Contents**

On November 6, 2013, the Company completed a PIPE financing, providing for the issuance and sale of an aggregate of 7,740,142 shares of its common stock to 52 accredited investors at a purchase price of six dollars (\$6.00) per share, for gross proceeds of approximately \$46.4 million.

On October 31, 2013, Ignyta, Inc. approved a 100-for-1 reverse stock split of its capital stock, and the Company approved a 3-for-1 reverse stock split of its capital stock (the Reverse Stock Splits). The par value of Ignyta, Inc.'s outstanding capital stock changed from \$0.0001 to \$0.00001 per share on such date. At the closing of the Reincorporation Merger, the par value of the Company's outstanding capital stock changed back from \$0.00001 to \$0.0001 per share. The stockholders' equity section of the accompanying financial statements and all share numbers disclosed throughout the financial statements have been retroactively adjusted to give effect to the Reverse Stock Splits and the Reincorporation Merger.

*Series A Convertible Preferred Stock*

During 2012, the Company issued 416,667 shares of Series A Preferred Stock at \$0.60 per share for proceeds consisting of \$250,000 in cash.

During 2011, the Company issued 416,667 shares of Series A Preferred Stock at \$0.60 per share for proceeds consisting of \$250,000 in cash.

On October 31, 2013, prior to the Reverse Stock Splits, the holders of shares of the Company's Series A Preferred Stock elected to convert all issued and outstanding shares of such preferred stock into shares of common stock at the applicable conversion rate, which was one-to-one.

*Series B Convertible Preferred Stock*

During 2012, the Company issued 1,835,000 shares of Series B Preferred Stock at \$3.00 per share for proceeds consisting of \$5,505,000 in cash.

On October 31, 2013, prior to the Reverse Stock Splits, the holders of shares of the Company's Series B Preferred Stock elected to convert all issued and outstanding shares of such preferred stock into shares of common stock at the applicable conversion rate, which was one-to-one.

**8. Stock-Based Compensation**

On June 11, 2014, the Company adopted the 2014 Plan. The 2014 Plan provides for the issuance of equity awards to employees and non-employees of 3,000,000 shares, plus one share for each share subject to a stock option that was outstanding under the 2011 Plan as of the effective date of the 2014 Plan that subsequently expires, is forfeited or is settled in cash.

On February 28, 2014, the Company adopted the Employment Inducement Incentive Award Plan (the Inducement Plan ). The Inducement Plan provided for the issuance of equity awards to new employees of 1,000,000 shares.

In 2011, the Company adopted the 2011 Plan. The 2011 Plan provided for the issuance of incentive stock options to employees and nonstatutory stock options, restricted stock awards, stock appreciation rights and stock bonuses to directors, employees and consultants. In February 2013, October 2013 and December 2013, the 2011 Plan was amended to, among other things, increase the number of shares of the Company s common stock available for issuance thereunder from 166,666 shares to 666,666 shares, to 712,652 shares and to 2,712,652 shares, respectively.

*Stock option activity*

There are a total of 3,000,000 shares of common stock reserved under the 2014 Plan, plus one share for each share subject to a stock option that was outstanding under the 2011 Plan as of the effective date of the 2014 Plan that subsequently expires, is forfeited or is settled in cash. As of June 30, 2014, 2,910,000 shares remain available under the 2014 Plan. There were a total of 2,712,652 shares of common stock reserved under the 2011 Plan. As of June 30, 2014, 1,607,071 shares remained available; however, under applicable rules of the NASDAQ Stock Market, the Company may not make additional grants under the 2011 Plan unless the 2011 Plan is approved by the Company s stockholders. The Company did not seek stockholder approval and adopted the 2014 Plan. In addition, there were 1,000,000 shares of common stock reserved under the Inducement Plan. As of June 30, 2014, 190,000 shares remained available under the Inducement Plan. From and after the effective date of the 2014 Plan, no additional equity grants may be made by the Company under the 2011 Plan or the Inducement Plan.

At the closing of the Reincorporation Merger, (i) each outstanding option to purchase, or other equity award relating to, Ignyta s common stock was deemed to constitute an option to purchase, or other equity award relating to, common stock of the Company with no change in the exercise price or other terms or provisions of the award, and (ii) the shares of Ignyta s common stock that remained available for issuance under the Ignyta Plans were deemed to relate to shares of the Company s common stock.

The options that are granted under the Ignyta Plans and the Inducement Plan are exercisable at various dates and will expire no more than ten years from their dates of grant. The exercise price of each option to be granted under the 2014 Plan shall be determined by the administrator of the 2014 Plan, which is the Company s Board of Directors or the Compensation Committee thereof, and shall not be less than 100% of the fair market value of the Company s common stock on the date the option is granted. Generally, options are granted with an exercise price equal to the fair market value of the Company s common stock on the date of the option grant. For holders of more than 10% of the Company s total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company s common stock on the date of grant and for a term not to exceed five years.



Table of Contents

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2011	12,500	\$ 0.18		\$
Granted	144,159	0.39		
Exercised				
Cancelled				
Balance at December 31, 2012	156,659	0.36		
Granted	1,061,325	4.60		
Exercised	(12,290)	0.24		
Expired	(2,154)	0.54		
Forfeited	(70,387)	0.45		
Balance at December 31, 2013	1,133,153	\$ 4.33	9.71	\$ 3,026,430
Granted	1,442,000	8.02		
Exercised	(12,962)	0.42		
Expired	(4,999)	0.58		
Forfeited	(237,036)	7.68		
Balance at June 30, 2014	2,320,156	\$ 6.31	9.56	\$ 6,457,975
Exercisable at June 30, 2014	135,838	\$ 0.67	8.51	\$ 1,144,042

The fair value of options granted to employees and non-employee directors was estimated at the date of grant using a Black-Scholes option pricing model with the weighted-average assumptions stated below.

	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013
Risk free interest rate	1.76%	0.00%
Dividend yield	0.00%	0.00%
Volatility	68.36%	0.00%

Weighted-average expected life of option (years)	<b>6</b>	<b>0</b>
	<b>Six Months Ended June 30, 2014</b>	<b>Six Months Ended June 30, 2013</b>
Risk free interest rate	<b>1.83%</b>	<b>1.18%</b>
Dividend yield	<b>0.00%</b>	<b>0.00%</b>
Volatility	<b>63.83%</b>	<b>59.82%</b>
Weighted-average expected life of option (years)	<b>6.02</b>	<b>5.99</b>

The estimated weighted-average per-share fair value of stock options granted to employees and non-employee directors for the three months ended June 30, 2014 and 2013 was \$4.51 and \$0.00, respectively and for the six months ended June 30, 2014 and 2013 was \$4.70 and \$0.33, respectively.

**Table of Contents**

The fair value of options granted to non-employees was estimated at the vesting date using a Black-Scholes option pricing model with the weighted-average assumptions stated below.

	<b>Three Months Ended June 30, 2014</b>	Three Months Ended June 30, 2013
Risk free interest rate	<b>2.52%</b>	0.00%
Dividend yield	<b>0.00%</b>	0.00%
Volatility	<b>68.42%</b>	0.00%
Weighted-average expected life of option (years)	<b>9.95</b>	0

The fair value of options granted to non-employees was estimated at the vesting date using a Black-Scholes option pricing model with the weighted-average assumptions stated below.

	<b>Six Months Ended June 30, 2014</b>	Six Months Ended June 30, 2013
Risk free interest rate	<b>2.50%</b>	2.05%
Dividend yield	<b>0.00%</b>	0.00%
Volatility	<b>68.37%</b>	59.25%
Weighted-average expected life of option (years)	<b>9.85</b>	10

The estimated weighted-average per-share fair value of stock options granted to non-employees for the three months ended June 30, 2014 and 2013 was \$6.94 and \$0.00, respectively, and for the six months ended June 30, 2014 and 2013 was \$6.65 and \$0.42, respectively.

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

*Expected Volatility* Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated or is expected to fluctuate during a period. The Company considered the historical volatility of peer companies and business and economic considerations in order to estimate the expected volatility, due to the Company not being 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.

*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 based on the simplified method as defined in Staff Accounting Bulletin 110. For non-employee options granted, this is the remaining contractual term of the option as of the reporting date.

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.

Stock-based compensation expense for employees and non-employees for the three months ended June 30, 2014 and 2013 was \$346,040 and \$16,602, respectively, and for the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014 was \$661,146, \$38,986 and \$1,025,759, respectively. For the three months ended June 30, 2014 and 2013, \$99,791 and \$9,884 was recorded to research and development expense, respectively, and \$246,249 and \$6,719 was recorded to general and administrative expense, respectively. For the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014, \$153,259, \$29,304 and \$380,992 was recorded to research and development expense, respectively, and \$507,887, \$9,682, and \$644,767 was recorded to general and administrative expense, respectively.

**Table of Contents**

As of June 30, 2014, there was an additional \$8,000,700 of total unrecognized compensation cost related to unvested stock-based awards granted under the Ignyta Plans and the Inducement Plan. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.57 years.

*Restricted stock activity*

In 2011, Ignyta sold 666,668 shares of restricted common stock for gross proceeds of \$2,000 in accordance with restricted stock purchase agreements with various advisors. Approximately 600,000 shares were vested immediately and the remaining 66,668 are subject to vesting requirements based on future service.

The terms of each of the agreements state that the Company has the right to repurchase the unvested shares of stock if the shareholder stops providing services to the Company. The Company repurchased 13,334 shares of common stock in 2012. The Company records stock-based compensation expense, calculated as the difference between the fair value of the common stock at each reporting period less the proceeds received, upon vesting of the restricted stock. Related stock-based compensation for the three months ended June 30, 2014 and 2013 was \$18,180 and \$2,040, respectively, and for the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014 was \$34,780, \$3,240 and \$64,760, respectively. All stock-based compensation relating to restricted stock was expensed to research and development. At June 30, 2014, 635,334 shares were vested and 18,000 shares remained unvested.

On May 20, 2013, in connection with Ignyta's merger with Actagene, Ignyta issued 1,583,336 shares of restricted common stock in exchange for the cancellation of all of the outstanding shares of Actagene (see Note 3). In February of 2014, in connection with the termination of employment of an employee, the Company repurchased 400,000 restricted shares. Of the remaining restricted shares, approximately 1,000,000 shares were vested immediately and 183,336 are subject to vesting requirements based on future service. The shares vest over four years, with one-third having vested in February 2014 and the remaining unvested shares vesting over the next 36 months. Related stock-based compensation for the three months ended June 30, 2014 and 2013 was \$16,831 and \$0, respectively, and for the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014 was \$121,404, \$0 and \$121,404, respectively. All stock-based compensation relating to restricted stock was expensed to research and development. At June 30, 2014, 1,133,952 shares were vested and 49,384 shares remained unvested.

All of the foregoing restricted stock was exchanged for shares of Ignyta, Inc. common stock in connection with the Merger and for the Company's common stock in connection with the Reincorporation Merger (see Note 2).

**9. Warrants**

On November 6, 2013, the Company issued Nerviano Medical Sciences S.r.l. ( NMS ) a warrant to acquire up to 16,667 shares of its common stock in connection with the license agreement between the Company and NMS. The warrant has an exercise price of \$6.00 per share and is exercisable at the option of the holder, in whole or in part, at any



time until November 6, 2018. The terms of such warrant provide for adjustments in the event of certain stock dividends, stock splits, recapitalizations, reclassifications and consolidations. Upon exercise, the aggregate exercise price of the warrant issued is payable by NMS in cash.

The Company recognized warrant expense of \$47,600 using a binomial model with an exercise price of \$6.00, risk free interest rate of 1.68%, volatility of 54.8%, and a useful life of 4.85 years. The entire amount was expensed to research and development in 2013.

During 2012, the Company issued a warrant to purchase 8,334 shares of Series B Preferred Stock in connection with the Loan Agreement (see Note 6). The exercise price of the warrant is \$3.00 per share.

On February 27, 2013, the Company issued a warrant to purchase up to a number of shares of Series B Preferred Stock equal to 5% of the amount loaned under the Loan Agreement on February 27, 2013 and thereafter, subject to adjustment as set forth in the warrant, including without limitation for stock combinations and splits (see Note 6). As a result, following the February 2013 and July 2013 advances under the Loan Agreement, the warrant became exercisable for 16,667 shares of the Company's Series B Preferred Stock. The exercise price of the warrant is \$3.00 per share and the warrant expires February 27, 2020.

The exercise price of the warrants issued in conjunction with the loan financing is protected against dilutive financing through the term of the warrants. Pursuant to ASC 815-15 and ASC 815-40, the fair value of the warrants was recorded as a derivative liability on the issuance dates.

**Table of Contents**

Each of the warrants was valued at the grant date and at the end of each reporting period thereafter.

The Company revalued all of the warrants at the end of each reporting period, and the estimated fair value of the outstanding warrant liability was \$181,800 and \$30,900 at June 30, 2014 and 2013, respectively. The change in the estimated fair value of the derivative liability resulted in other expense of \$52,400 for the six month period ended June 30, 2014 and other income of \$5,700 for the six month period ended June 30, 2013.

The derivative liabilities were valued at their issuance dates and at the end of each reporting period using a binomial pricing model and the following weighted average assumptions:

	<b>June 30, 2014</b>	June 30, 2013
Expected volatility	<b>69.5%</b>	39.6%
Risk-free interest rate	<b>1.77%</b>	1.69%
Dividend yield	<b>0.00%</b>	0.00%
Remaining expected term of underlying securities (years)	<b>5.57</b>	6.67

**10. Income Taxes**

The Company maintains deferred tax assets that reflect the net tax effects of temporary differences between the book values of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, deferred revenue and stock-based compensation. In assessing the potential for realization of deferred tax assets, the Company considers whether it is more likely than not that some or all of the deferred tax assets will not be realized.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. The Company considers projected future taxable income and planning strategies in making this assessment. Based on the level of historical operating results and projections for the taxable income for the future, the Company has determined that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance to reduce deferred tax assets to zero. The Company may not ever be able to realize the benefit of some or all of the federal and state loss carryforwards, either due to ongoing operating losses or due to ownership changes, which limit the usefulness of the loss carryforwards.

**11. Commitments and Contingencies***Operating leases*

The Company leases office space under non-cancelable operating leases expiring on various dates through October 2019. Rent expense under those operating leases for the three months ended June 30, 2014 and 2013 was \$111,204 and \$41,081, respectively,

and for the six months ended June 30, 2014 and 2013, and for the period from inception (August 29, 2011) through June 30, 2014 was \$158,680, \$59,382 and \$335,551, respectively.

The Company leases lab equipment under a non-cancelable operating lease that expires in March 2016. Monthly payments are \$5,758. Rent expense under that operating lease for the three months ended June 30, 2014 and 2013 was \$22,126 and \$16,368, respectively, and for the six months ended June 30, 2014 and 2013, and for the period from inception (August 29, 2011) through June 30, 2014 was \$44,252, \$16,368 and \$104,872, respectively.

Future minimum lease payments required under the operating leases are as follows:

<i>Twelve Months Ending June,</i>	
2015	\$ 475,500
2016	788,300
2017	758,600
2018	781,300
2019	804,700
Thereafter	274,900
<b>Total</b>	<b>\$ 3,883,300</b>

#### *License agreements*

The Company has entered into a license agreement with NMS which became effective on November 6, 2013, whereby the Company obtained an exclusive license in certain of NMS Active Pharmaceutical Ingredients (APIs) and certain NMS IP rights upon the effective date of the agreement. An initial payment of \$7,000,000 was paid in November 2013. The entire amount was expensed to research and development in 2013 as no future benefit can be determined at this time. In addition, NMS was issued on November 6, 2013 a five year warrant to purchase 16,667 shares of our common stock at an exercise price per share of six dollars (\$6.00). Tiered royalties in the low single digits to mid double digits will be paid based upon aggregate annual net sales. The 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. The first such milestone payment is not due until the Company elects to initiate the first randomized Phase II clinical study, which, based on its current estimates and certain assumptions, the Company anticipates could occur as early as 2015. The Company is obligated under the terms of the license agreement to engage NMS to perform services valued at \$1 million or more between the effective date of the license agreement and December 31, 2014, which services could include, among others at the Company's election, manufacture and supply services, technology transfer activities, preclinical activities, process development activities and assay development activities. As of June 30, 2014, this obligation was fully met.

**Table of Contents**

In March 2012, the Company entered into a license agreement with a university for the use of certain patented rights relating to molecular diagnostics. The Company delivered notice to the university of the Company's exercise of its right to terminate the license agreement, effective as of April 2014. Under the agreement, the Company was required to make annual license payments of \$15,000. The Company made the first license payment under the agreement in 2012 and its annual license payment under the agreement in 2013. These payments were amortized monthly and expensed to research and development.

On March 31, 2014, the Company entered into an agreement with a contract research organization for clinical studies to be conducted both within and outside the U.S., at an estimated cost of approximately \$10 million over a two-year period.

**12. Concentrations**

*Credit risk*

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

Our cash is invested in accordance with a policy approved by our Board of Directors which specifies the categories, allocations, and ratings of securities we may consider for investment. We do not believe our cash, cash equivalents and available-for-sale securities have significant risk of default or illiquidity. We made this determination based on discussions with our treasury managers and a review of our holdings. While we believe our cash, cash equivalents and available-for-sale securities are well diversified and do not contain excessive risk, we cannot provide absolute assurance that our investments will not be subject to future adverse changes in market value.

**13. Related Parties**

In 2012, the Company executed an employee lease agreement with its majority stockholder. Under the terms of the agreement, the Company is reimbursed for certain administrative services provided to the related party. In addition, the Company was reimbursed for various operating expenses related to shared utilities and telecommunications and/or may make payments to its majority shareholder for these shared operating expenses.

Total reimbursements received during the three months ended June 30, 2014 and 2013 was \$0 and \$95, respectively, and for the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014 was \$0, \$5,372 and \$19,397, respectively. There was \$0 in accounts receivable at June 30, 2014 and 2013, respectively. Total payments made during the three months ended June 30, 2014 and 2013 was \$453 and \$19,241, respectively, and for the six months ended June 30, 2014 and 2013 and the period from inception (August 29, 2011) through June 30, 2014 was \$1,165, \$22,409 and \$40,215, respectively.

In May 2013, the Company and Actagene effected a merger pursuant to which Actagene merged with and into the Company. The majority stockholder of Ignyta was also the majority stockholder of Actagene, and representatives of the majority stockholder controlled the day to day operations and were on the board of directors of each entity (see Note 3).

**14. 401(k) Plan**

In 2014, the Company established a defined contribution plan, organized under Section 401(k) of the Internal Revenue Code, which allows employees who have completed at least one month of service and have reached age 21 to defer up to 100% of their pay on a pre-tax basis. The Company does not contribute a match to the employees' contribution.

**15. Subsequent Events**

On August 4, 2014, the Company entered into a license agreement with NMS granting the Company an exclusive license to two new drug development programs, which the Company will refer to as RXDX-103 and RXDX-104, and related intellectual property. Under the license agreement, the Company will make an initial payment to NMS of \$3.5 million by August 14, 2014. Tiered royalties in the mid-single digits to low double digits will be paid based upon aggregate annual net sales. The agreement also requires that the Company makes development and regulatory milestone payments to NMS of up to \$102.0 million in the aggregate if specified clinical study initiations and regulatory approvals are achieved across multiple products or indications.

**Table of Contents****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, 2013, 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, 2013. 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, 2013 and the caption "Risk Factors" in this Quarterly Report on Form 10-Q.*

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

*On June 12, 2014, Ignyta, Inc. merged with and into Ignyta Operating, with Ignyta Operating surviving the merger and changing its name to "Ignyta, Inc." This merger had no material impact on the accounting of the company.*

*Unless the context indicates or otherwise requires, the terms "we," "us," "our" and "our company" refer to (i) Ignyta Operating for discussions relating to periods before and through October 31, 2013, (ii) Ignyta and its consolidated subsidiary, Ignyta Operating, for discussions relating to periods after October 31, 2013 and through June 12, 2014, and (iii) Ignyta, Inc., the surviving company to the June 12, 2014 merger, for discussions relating to periods after June 12, 2014.*

**Overview**

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

and into our company on that date. On June 12, 2014, Ignyta Operating merged with and into Ignyta, with Ignyta Operating surviving the merger, resulting in our reincorporation from Nevada to Delaware. In connection with this merger, each share of Ignyta common stock was converted into one share of Ignyta Operating common stock, and we changed our name to Ignyta, Inc.

We are a precision medicine biotechnology company dedicated to discovering or acquiring, then developing and commercializing, targeted new drugs for cancer patients whose tumors harbor specific molecular alterations. We are pursuing an integrated drug and diagnostic, or Rx/Dx, strategy, where we anticipate pairing each of our product candidates with biomarker-based companion diagnostics, developed by us or by third parties with which we may partner, that are designed to identify the patients that are most likely to benefit from the use of the drugs we may develop. Our current development plans focus on our lead product candidate: RXDX-101, a tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in two Phase I/II clinical studies in molecularly defined patient populations for the treatment of solid tumors. We have another product candidate, RXDX-102, a tyrosine kinase inhibitor directed to the Trk family of tyrosine kinase receptors, which we have designated as a back-up compound to RXDX-101. We have entered into a license agreement with Nerviano Medical Sciences, S.r.l., or NMS, granting us exclusive global development and marketing rights to RXDX-101 and RXDX-102, which became effective on November 6, 2013.

## **Table of Contents**

In August 2014, we entered into a second license agreement with NMS pursuant to which NMS granted us exclusive global development and marketing rights to RXDX-103, a development candidate stage inhibitor of the cell division cycle 7-protein, or Cdc7, kinase and RXDX-104, a lead optimization stage program designed to inhibit the RET tyrosine kinase.

We also have three discovery stage programs, Spark-1, Spark-2 and Spark-3, directed to emerging oncology targets identified through mining of our database of information from proprietary and publicly available tumor samples, called Oncolome . Our strategy is to leverage the biomarker insights that we gain through our genetic and epigenetic mining of our Oncolome database and the knowledge of cancer biology of our management and drug discovery team, with the goal of discovering or acquiring, validating, developing and commercializing a pipeline of novel product candidates for the treatment of cancer.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, assembling our core capabilities in genetic and epigenetic based biomarker and drug target discovery, identifying potential product candidates and developing such candidates. Our product candidate development operations include preparing, managing and conducting preclinical and clinical studies and trials, preparing regulatory submissions relating to those product candidates and establishing and managing relationships with third parties in connection with all of those activities. We expect that in the future our operations may also, if regulatory approval is obtained, include pursuing the commercialization of our product candidates.

## **Financial Operations Overview**

### *Revenue*

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

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

### *Research and Development Expenses*

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

expenses incurred under agreements with third parties, including consultants and advisors we engage for research-related services and any contract research organizations, or CROs, that we may engage in connection with conducting preclinical and clinical activities on our behalf;

employee-related expenses, including salaries, benefits and stock-based compensation expense;

the cost of laboratory supplies;



facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other operating costs; and

license fees.

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 have not yet begun tracking our internal and external research and development costs on a program-by-program basis. As such, we do not have historical research and development expenditures by program and we use our employee and infrastructure resources across multiple research and development programs.

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 RXDX-101, RXDX-103 and RXDX-104, and drug discovery activities for the development of our Spark-1, Spark-2 and Spark-3 programs. All of those research and development programs are in the early stage, and since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect research and development costs relating to each of those programs to increase significantly for the foreseeable future. However, the successful development of any of those 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 of these product candidates, or whether any of these 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

**Table of Contents**

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 U.S. Food and Drug Administration, or FDA, and other applicable regulatory authorities, are beyond our control, including the uncertainty of:

establishing an appropriate safety profile with toxicology studies adequate to submit to the FDA in an Investigational New Drug application, or IND, or comparable applications to foreign regulatory authorities;

successful enrollment in and adequate design and completion of clinical trials;

receipt of marketing approvals from applicable regulatory authorities, including the FDA and comparable foreign authorities;

establishing commercial manufacturing capabilities or, more likely, seeking to establish arrangements with third-party manufacturers;

obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;

launching commercial sales of the products, if and when approved, including establishing an internal sales and marketing force and/or establishing relationships with third parties for such purpose;

developing and commercializing, individually or with third-party collaborators, companion diagnostics; and

a continued acceptable safety profile of the products following approval, if any.

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

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal 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 value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We periodically evaluate our estimates and judgments, including those described in greater detail below, in light of changes in circumstances, facts and experience.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. Our significant accounting policies are described in more detail in the notes to our financial statements included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2013, or our Form 10-K. We believe the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments are as follows:

#### *Revenue Recognition*

To date, we have not generated any material revenue.

## **Table of Contents**

### *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.

### *Cash and Cash Equivalents*

We consider 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.

### *Investments*

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

### *Stock-Based Compensation*

We account for stock-based compensation in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation Stock Compensation*, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

We account for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

### *Derivative Liabilities*

We account for our warrants as either equity or liabilities based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on our balance sheet at their fair value on the date of issuance and revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. We estimate the fair

value of these liabilities using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future events, expected volatility, expected life, yield and risk-free interest rate.

**Recently Issued Accounting Pronouncements**

There are no recent accounting pronouncements likely to have a material impact on the financial statements.

**Table of Contents****Results of Operations***Comparison of the Three Months Ended June 30, 2014 and 2013*

The following table summarizes our results of operations for the three months ended June 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	<b>Three Months ended June 30, 2014</b>		<b>2013</b>	<b>Dollar change</b>	<b>% change</b>
	<b>(in thousands)</b>				
Revenue	\$ 150	\$	\$ 150	\$ 150	N/A %
Operating expenses:					
Research and development	3,576	585	2,991	511	511
General and administrative	2,039	527	1,512	287	287
Loss from operations	(5,465)	(1,112)	(4,353)	391	391
Other income (expense)	42	(29)	71	(245)	(245)
Provision for income taxes					
Net loss	\$ (5,423)	\$ (1,141)	\$ (4,282)	375%	

*Revenue.* We recorded revenue of \$150,000 for the three months ended June 30, 2014. We did not record any revenue for the three months ended June 30, 2013. The increase was due to a one-time service-fee for research services conducted in the second quarter of 2014.

*Research and Development Expense.* Research and development expense increased by approximately \$3.0 million for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013, an increase of 511%. The increase in research and development expenses was primarily attributable to an increase in activities relating to development of our RXDX-101 product candidate. We also incurred an increase between periods for personnel expenses related to hiring and engaging additional employees and consultants to help us advance our product candidates and facilities related expenses as a result of the expansion of our leased facilities space.

*General and Administrative Expense.* General and administrative expenses increased by approximately \$1.5 million for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013, an increase of 287%. The increase in general and administrative expenses was primarily attributable to increases in personnel, audit, legal and intellectual property costs, some of which resulted from activities relating to operating as a public company, and facilities related expenses as a result of the expansion of our leased facilities space.

*Other Income (Expense).* Other income increased by approximately \$0.1 million for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013, an increase of 245%. The increase in other income was attributable to interest income earned on our available for sale securities, offset by increased interest owed under our loan agreement with Silicon Valley Bank, or SVB, as well as the change in the fair value of the warrant liability associated with the warrants we issued to SVB.

*Comparison of the Six Months Ended June 30, 2014 and 2013*

Edgar Filing: Ignyta, Inc. - Form 10-Q

The following table summarizes our results of operations for the six months ended June 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	<b>Six Months ended June 30,</b>		<b>Dollar change</b>	<b>% change</b>
	<b>2014</b>	<b>2013</b>		
	<b>(in thousands)</b>			
Revenue	\$ 150	\$	\$ 150	N/A %
Operating expenses:				
Research and development	5,758	1,221	4,537	372
General and administrative	3,795	904	2,891	320
Loss from operations	(9,403)	(2,125)	(7,278)	342
Other income (expense)	(121)	(30)	(91)	303
Provision for income taxes	5	2	3	150
Net loss	\$ (9,529)	\$ (2,157)	\$ (7,372)	342%

*Revenue.* We recorded revenue of \$150,000 for the six months ended June 30, 2014. We did not record any revenue for the six months ended June 30, 2013. The increase was due to a one-time service-fee for research services conducted in the second quarter of 2014.

## **Table of Contents**

*Research and Development Expense.* Research and development expense increased by approximately \$4.5 million for the six months ended June 30, 2014 as compared to the six months ended June 30, 2013, an increase of 372%. The increase in research and development expenses was primarily attributable to an increase in activities relating to development of our RXDX-101 product candidate. We also incurred an increase between periods for personnel expenses related to hiring and engaging additional employees and consultants to help us advance our product candidates and facilities related expenses as a result of the expansion of our leased facilities space.

*General and Administrative Expense.* General and administrative expenses increased by approximately \$2.9 million for the six months ended June 30, 2014 as compared to the six months ended June 30, 2013, an increase of 320%. The increase in general and administrative expenses was primarily attributable to increases in personnel costs and investor relations, audit, legal and intellectual property costs, some of which resulted from activities relating to operating as a public company and completion of our March 2014 public offering of our common stock, and facilities related expenses as a result of the expansion of our leased facilities space.

*Other Income (Expense).* Other expense increased by approximately \$0.1 million for the six months ended June 30, 2014 as compared to the six months ended June 30, 2013, an increase of 303%. The increase in other expense was attributable to increased interest owed under our loan agreement with SVB as well as the change in the fair value of the warrant liability associated with the warrants we issued to SVB, partially offset by an increase in interest income.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

Since our inception, and through June 30, 2014, we have raised an aggregate of approximately \$125 million to fund our operations, of which approximately \$55 million was received from our issuance and sale of our common stock in an underwritten public offering in March 2014, approximately \$54 million was received from our issuance and sale of our common stock in two private placements in November 2013, approximately \$6 million was received from our issuance and sale of our preferred stock and \$10.0 million was received from the incurrence of indebtedness under our December 2013 loan agreement with SVB. As of June 30, 2014, we had also received a small amount of funding from our issuance of common stock upon the exercise from time to time of stock options, and from our issuance of common stock to our founders in August and September 2011. As of June 30, 2014, we had approximately \$95.1 in cash, cash equivalents and available-for-sale securities, consisting of approximately \$34.6 million in cash and cash equivalents and approximately \$60.6 million in available-for-sale securities.

*Public Offering.* In March 2014, we issued an aggregate of 6,031,750 shares of our common stock in an underwritten public offering. All of the shares issued in the public offering were sold by the underwriters at a purchase price per share of \$9.15, for aggregate gross proceeds of approximately \$55.2 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately \$51.6 million.

*Loan Agreement with SVB.* On December 31, 2013, we entered into our new loan agreement with SVB and received the funding of the full \$10.0 million principal amount thereunder. The loan agreement replaced our prior loan agreement with SVB, which had a principal amount of \$1.5 million that was replaced by the advance of the principal amount under the new loan agreement. The amount loaned to us under the new loan agreement bears interest at a rate of 6.92%, and is payable in 36 equal monthly installments commencing after a 12-month period of interest-only payments, such that all amounts owed under the new loan agreement will mature on December 1, 2017. Upon such maturity date, we will also owe to SVB a final payment of \$1,050,000, equal to 10.50% of the full principal amount under the new loan agreement. Pursuant to the new 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, and, all amounts owed thereunder will begin to bear interest at a rate of 11.92% and could be declared due and payable by SVB upon the occurrence of an event of default.

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

*Preferred Stock Financings.* We received approximately \$6.0 million from the issuance and sale of our series A preferred stock and our series B preferred stock prior to the closing of our October 31, 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 Ignyta, all then-outstanding shares of each series of our preferred stock were voluntarily converted by the holders thereof into shares of our common stock in accordance with our certificate of incorporation.

**Table of Contents***Cash Flows*

The following table provides information regarding our cash flows for the six months ended June 30, 2014 and 2013:

	<b>Six Months ended, June 30,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
Net cash (used in) operating activities	\$ (6,252)	\$ (2,056)
Net cash (used in) investing activities	(62,573)	(247)
Net cash provided by financing activities	51,586	506
Net increase (decrease) in cash and cash equivalents	\$ (17,239)	\$ (1,797)

*Net Cash Used in Operating Activities.* The use of cash in all 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 \$6.3 million during the six months ended June 30, 2014 compared to approximately \$2.1 million during the six months ended June 30, 2013. The increase in cash used in operating activities was driven primarily by our net loss.

*Net Cash Used in Investing Activities.* Net cash used in investing activities was approximately \$62.6 million during the six months ended June 30, 2014 compared to approximately \$247,000 during the six months ended June 30, 2013. The cash used in investing activities was primarily the result of investments in available-for-sale securities and to a lesser extent purchases of fixed assets.

*Net Cash Provided by Financing Activities.* Net cash provided by financing activities was approximately \$51.6 million during the six months ended June 30, 2014 compared to approximately \$506,000 during the six months ended June 30, 2013. The cash provided by financing activities for the six months ended June 30, 2014 was primarily the result of our March 2014 public offering of common stock.

*Funding Requirements*

We expect our expenses to increase in connection with the ongoing development and manufacturing of RXDX-101, RXDX-103 and RXDX-104 and as we continue the research and development of our Spark-1, Spark-2 and Spark-3 programs. In addition, if we obtain marketing approval for any of our product candidates in the future, which we anticipate would not occur for several years if at all, we expect we would then incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of any collaborators with whom we may engage. Further, we expect to incur additional costs associated with operating as a public company.

Even after giving effect to our March 2014 and November 2013 common stock offerings and our December 2013 loan agreement with SVB, we expect to need to obtain additional funding in order to continue our operations and pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and available-for-sale securities will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. 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 product candidates;

the scope, progress, results and costs of companion diagnostic development for our product candidates;

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 achievement of development milestones that trigger payments due to our licensing partners;

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;

## **Table of Contents**

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. We do not have any committed external source of additional funds. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the ownership interest of existing equityholders 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 to 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.

## **Off-Balance Sheet Arrangements**

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

## **Caution on Forward-Looking Statements**

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue to anticipate, intend, seek, plan, expect, should or would, or the negative of these terms or other comparable terms. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the results of our research and development activities, including uncertainties relating to the discovery of potential product candidates and the preclinical and clinical testing of our product candidates; the early stage of our product candidates presently under development; our 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 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 retain or hire key scientific or management personnel; our ability, with partners, to validate, develop and obtain regulatory approval of companion diagnostics for our product candidates; our ability to protect our intellectual property rights, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; our ability to develop successful sales and marketing capabilities in the future as needed; the size and growth of the potential markets for any of our product candidates, and the rate and degree of market acceptance of any of our product candidates; competition in our industry; the impact of healthcare reform legislation; 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.

---

**Table of Contents**

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As a smaller reporting company we are not required to provide the information required by this item in this report.

**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 June 30, 2014 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, 2013 includes a detailed discussion of our risk factors under the heading Part I, Item 1A Risk Factors. Set forth below are certain changes from the risk factors previously disclosed in our Annual Report on Form 10-K. You should carefully consider the risk factors discussed in our Annual Report on Form 10-K as well as the other information in this report before deciding whether to invest in shares of our common stock. The occurrence of any of the risks discussed in the Annual Report on Form 10-K or this report could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective third party owners.*

***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, 2013 and the six months ended June 30, 2013 was \$14.2 million and \$9.5 million, respectively. As of June 30, 2014, we had an accumulated deficit of \$25.1 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are currently focused primarily on the development of RXDX-101, RXDX-103, RXDX-104, Spark-1, Spark-2 and Spark-3, which we believe will result in our continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of our products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, 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.

---

**Table of Contents**

***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, reduce or eliminate our product development programs or commercialization efforts and could cause our business to fail.***

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

Even after giving effect to the proceeds received from our March 2014 and November 2013 common stock offerings and our December 2013 loan agreement with SVB, we expect to require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner than we currently anticipate if we choose to and are able to expand more rapidly than we currently anticipate. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the ongoing development of RXDX-101 and our other product candidates, and if we acquire rights to additional product candidates. For example, in February 2014 we submitted an IND to the FDA for RXDX-101, which IND became active with the FDA in March 2014. In July 2014, we initiated a new, global Phase I/II clinical trial of oral RXDX-101 in adult patients with metastatic cancer detected to be positive for relevant molecular alterations. We anticipate that this clinical trial will involve clinical sites in the United States, Europe, and Asia.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs and/or cause us to spend our cash resources faster than we expect. Accordingly, we 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 by founders and other investors and the incurrence of debt, and we expect to continue to do so in the foreseeable future. We may also seek funding through collaborative arrangements. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. 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 product.

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

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



To date, we have invested significant efforts in the acquisition of our four drug programs from NMS. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize RXDX-101, with RXDX-102 as a back-up compound in case the development of RXDX-101 is not successful, RXDX-103 and RXDX-104. Our business depends entirely on the successful development, clinical testing and commercialization of these and any other product candidates we may seek to develop in the future, which may never occur.

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

conduct substantial clinical development;

manage clinical, preclinical and manufacturing activities;

achieve regulatory approval in multiple jurisdictions;

establish manufacturing relationships for the supply of the applicable product candidate;

build a commercial sales and marketing team, if we choose to market any such product ourselves, or enter into a collaboration to access sales and marketing functions;

---

**Table of Contents**

develop and implement marketing strategies;

develop and/or work with third-party collaborators to develop companion diagnostics and conduct clinical testing and achieve regulatory approvals for those companion diagnostics; and

invest significant additional cash in each of the above activities.

If the results of our ongoing RXDX-101 Phase I/II clinical trials are not successful, we may not be able to use those results as the basis for advancing the product candidate into further clinical development. In that case, we may not have the resources to conduct new clinical trials, and/or we may determine that further clinical development of this product candidate is not justified and may decide to discontinue the program. Clinical testing of RXDX-102 would not commence unless the development of RXDX-101 is not successful, but the results of any future preclinical studies or clinical trials of RXDX-102, if unsuccessful, could lead to our abandonment of the development of that product candidate as well. If the results of preclinical testing for RXDX-103 or RXDX-104 are not successful, we may not be able to use those results as the basis for advancing the product candidate into further development. If studies of these product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed.

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

We have only recently licensed the rights to develop our product candidates from NMS, and the development of those product candidates prior to our license was conducted wholly by NMS or any third parties with which it had contracted. As a result, we were not involved with nor did we have any control over any of those development activities. In addition, with respect to RXDX-104, we will not assume control over development activities until the earlier of December 31, 2014 or the identification by NMS of a lead development candidate. Because we had no input on NMS's development activities relating to these product candidates, we may discover that all or certain elements of the trials and studies performed by NMS have not been in compliance with applicable regulatory standards or have otherwise been deficient. For instance, the development of each of these product candidates to date has been conducted only in Europe. As a result, although we may find that those studies meet the standards of applicable European regulatory bodies, the structure and design of those clinical trials and preclinical studies may not meet applicable FDA standards to allow immediate further development of those product candidates in the United States, and also may not meet the standards of applicable regulatory authorities in any non-European foreign country in which we desire to pursue marketing approval for these product candidates. If the studies conducted by NMS are not in full compliance with applicable regulatory standards or are otherwise not eligible for continued development in the United States, then we may be forced to conduct new studies in order to progress their development, which we may not have the funding or other resources to complete and which would severely delay any of our development plans for these product candidates. Any such deficiency in the prior development of these product candidates would significantly harm our business plans and prospects.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Additionally, any positive results of preclinical studies and early clinical trials of a product candidate may not be predictive of the results of later-stage clinical trials, such that product

candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in earlier studies. For example, although the preclinical and early clinical results for our lead product candidate have been promising, those results and the results that may be generated in the ongoing Phase I/II clinical trials for RXDX-101 do not imply that later clinical trials will demonstrate similar results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. The results of any future clinical trials we conduct may not be successful.

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

obtaining regulatory approval to commence a trial;

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

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

**Table of Contents**

enrolling suitable patients to participate in a trial;

developing and validating companion diagnostics on a timely basis;

changes in formulation, dosing or administration regimens;

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

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

regulators instituting a clinical hold due to observed safety findings;

adding new clinical trial sites; or

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

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

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

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

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

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

the severity of the disease under investigation;

the frequency of the molecular alteration we are seeking to target in the applicable trial;

the willingness of clinical sites and principal investigators to subject candidate patients to molecular screening;

the eligibility criteria for the study in question;

the perceived risks and benefits of the product candidate under study;

the availability of other treatment options;

the extent of the efforts to facilitate timely enrollment in clinical trials;

the patient referral practices of physicians;

the ability to monitor patients adequately during and after treatment; and

the proximity and availability of clinical trial sites for prospective patients.

---

**Table of Contents**

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

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

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

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

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

regulatory authorities may withdraw approvals of such product;

regulatory authorities may require additional warnings on the product's label;

we may be required to create a medication guide for distribution to patients that outlines the risks of such side effects;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

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

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

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

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

---

**Table of Contents**

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

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

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our preclinical studies and clinical trials or commercial quantities of any product candidates that may obtain regulatory approval. As a result, we expect that we will need to rely completely on third-party manufacturers for those services. We currently have a limited supply of RXDX-101. We have entered into non-exclusive clinical supply agreements with two independent third parties. We do not currently have arrangements in place for commercial supply of bulk drug substance. We may not be able to establish these or any other supply relationship when needed, on reasonable terms, or at all. Any failure to secure sufficient supply of our product candidates for preclinical or clinical testing or, in the future, commercial purposes would materially harm our operations and financial results.

We expect that the facilities to be used by any contract manufacturers we engage to manufacture our product candidates will be inspected by the FDA in connection with any NDA that we submit. We will not control the manufacturing process of, and will be dependent on, our contract manufacturing partners for compliance with cGMPs for the manufacture of clinical and, if regulatory approval is obtained, commercial quantities of our product candidates. If any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our product candidates or commercializing our products, if approved, unless and until we could engage a substitute contract manufacturer that could comply with such requirements, which we may not be able to do. Any such failure by any of our contract manufacturers would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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



produce any of our product candidates that gain regulatory approval, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

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

With respect to our lead product candidate, we are aware of two agents that have been approved by the FDA for ALK-positive NSCLC, Pfizer's Xalko®/crizotinib and Novartis' Zykadia®/ceritinib. We are also aware of several other products in development targeting TrkA, TrkB, TrkC, ROS1, ALK, RET and/or Cdc7 for the treatment of cancer, some of which may be in a more advanced stage of development than our product candidates. There are also many other compounds directed to other molecular targets that are in clinical development by a variety of companies to treat cancer types that we may choose to pursue with RXDX-101, RXDX-103 and RXDX-104.

## Table of Contents

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

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

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

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

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

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

loss of revenues from product sales; and

the inability to commercialize our product candidates.

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

---

**Table of Contents**

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

We have in-licensed from NMS the use, development and commercialization rights for RXDX-101, RXDX-102, RXDX-103 and RXDX-104. 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 our license agreements with NMS, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential product candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of either of our license agreements with NMS, or any future license agreement we may enter on which our business or product candidates are dependent, NMS or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby extinguish our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. The loss of the rights licensed to us under our license agreements with NMS, or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

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

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any product candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered product candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our product candidates.

Our license agreements with NMS grant us an exclusive, worldwide license under a portfolio of patents and patent applications directed to the RXDX-101, RXDX-102, RXDX-103 and RXDX-104 composition of matter, which begin to expire in 2029 for the patents and applications relating to RXDX-101, in 2028 for the patents and applications relating to RXDX-102, in 2027 for the patents and patent applications relating to RXDX-103 and in 2033 for the patent applications relating to RXDX-104. 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, because filing, prosecuting and enforcing patents in multiple jurisdictions can be expensive, we may elect to pursue patent protection relating to our product candidates in only certain jurisdictions. As a result, competitors would be permitted to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, any of which could compete with our product candidates.

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

---

**Table of Contents**

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

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

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

While we expect that we will generally seek to gain the right to fully prosecute any patents covering product candidates we may in-license from third-party owners, there may be instances when platform technology patents that cover our product candidates remain controlled by our licensors. For instance, NMS has retained certain patent prosecution rights under our license agreements relating to RXDX-101, RXDX-102, RXDX-103 and RXDX-104. If any of our current or future licensing partners that retain the right to prosecute patents covering the product candidates we license from them fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected product candidates may suffer.

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

As of August 1, 2014, we had 36 employees, 33 of whom were full-time and three of whom were part-time. As our development and commercialization plans and strategies develop, we expect to need additional research, development, managerial, operational, sales, marketing, financial, accounting, legal and other resources. Future growth would impose significant added responsibilities on members of management, including:

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

effectively managing our discovery research and preclinical development;

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

effectively managing our internal development efforts;

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

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

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

improving our managerial, development, operational and finance systems.

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

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

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. To the extent we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a cumulative change in equity ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes to offset its post-ownership change income and taxes may be limited. We may have experienced an ownership change as a result of our October 31, 2013 merger transaction and/or our November 2013 and

**Table of Contents**

March 2014 common stock offerings and may experience one or more ownership changes as a result of future transactions in our stock, and as a result we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. As of December 31, 2013, we had federal and state net operating loss carryforwards of approximately \$7.3 million that could be limited if the merger or the common stock offerings resulted in an ownership change, or if we experience any other ownership change, which could potentially result in increased future tax liability to us.

***There may not be a viable trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.***

Our common stock had not been publicly traded on the NASDAQ Capital Market prior to our public offering in March 2014. The trading market for our common stock on the NASDAQ Capital Market has been limited, and an active trading market for our shares may not be sustained. As a result of these and other factors, you may be unable to sell your shares at a price that is attractive to you, or at all. Further, an inactive trading market may also impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

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

The price for our common stock currently is, and is likely to continue to be, highly volatile, and could be subject to wide fluctuations. That price fluctuation could be in response to various factors, some of which may be beyond our control. These factors are discussed in this Risk Factors section, and elsewhere in this Quarterly Report on Form 10-Q, as well as in the Risk Factors and other sections of our Annual Report on Form 10-K, as updated by our subsequent filings under the Exchange Act. These factors include, without limitation:

the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;

our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

actual or anticipated adverse results or delays in our clinical trials;

our failure to successfully commercialize our product candidates, if approved;

unanticipated serious safety concerns related to the use of any of our product candidates;

adverse regulatory decisions;

additions or departures of key scientific or management personnel;



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

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

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

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

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

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

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

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

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

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

issuances of debt or equity securities;

**Table of Contents**

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

trading volume of our common stock;

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

general political and economic conditions;

effects of natural or man-made catastrophic events; and

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

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks could have a dramatic and material adverse impact on the market price 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 August 1, 2014, a total of 19,579,588 shares of our common stock were outstanding. Of those shares, approximately 15,053,768 were freely tradable, without restriction, in the public market. Such shares represented 76.9% of our outstanding shares of common stock as of that date. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline. Additionally, the 4,516,469 outstanding shares of our common stock that we issued to our stockholders in connection with the closing of the October 2013 merger will become freely tradable upon the lapse of securities law restrictions on their resale, which could occur under Rule 144 after the end of the 12-month period following November 1, 2013, the date on which we initially filed with the SEC our Current Report on Form 8-K containing Form 10 information.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act 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.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of securities or industry analysts covering our business downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

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

We were not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to our October 2013 merger. Our management team and Board of Directors need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting

## **Table of Contents**

staff and engaging consultants to assist in designing and implementing such procedures. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

***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 August 1, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 29.4% of our outstanding voting stock (which includes shares they had the right to acquire within 60 days). Accordingly, our directors and executive officers and large stockholders have significant influence over our affairs due to their substantial ownership coupled with the positions of some of these stockholders on our management team, and have substantial voting power to approve matters requiring the approval of our stockholders. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership in our Board of Directors and management team and certain other large stockholders may prevent or discourage unsolicited acquisition proposals or offers for our common stock that some of our stockholders may believe is in their best interest.

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

Our second amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of our common stock and up to 10,000,000 shares of preferred stock with the rights, preferences and privileges that our Board of Directors may determine from time to time. In addition to capital raising activities such as public and private placements of our common stock, other possible business and financial uses for our authorized capital stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plans, or other transactions and corporate purposes that our board of directors deems are in the best interest of our company. Additionally, shares of our capital stock could be used for anti-takeover purposes or to delay or prevent changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may not enhance stockholder value, they may have rights, preferences and privileges that are superior to those of our common stock, and they may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

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

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

could cause the market price of our common stock to decline. In addition, any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.***

Our second amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

**Table of Contents**

a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;

advance notice requirements for stockholder proposals and nominations for election to our board of directors;

a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our second amended and restated certificate of incorporation; and

the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our second amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

**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.



**Table of Contents****Item 6. Exhibits****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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).
10.1	Ignyta, Inc. Employment Inducement Incentive Award Plan and form of stock option agreement thereunder (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 1, 2014).
10.2	Third Amendment to Lease between Ignyta, Inc. and BMR-Coast 9 LP dated April 18, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 23, 2014).
10.3#	Form of Indemnification Agreement by and between Ignyta, Inc. and each of its current directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K12B filed with the SEC on June 13, 2014).



Edgar Filing: Ignyta, Inc. - Form 10-Q

10.4#	Ignyta, Inc. 2014 Incentive Award Plan (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K12B filed with the SEC on June 13, 2014).
10.5#	Form of Stock Option Agreement under the Ignyta, Inc. 2014 Incentive Award Plan (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K12B filed with the SEC on June 13, 2014).
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.

# Management contract or compensatory plan or arrangement.

In accordance with Regulation S-T, XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, and is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not otherwise subject to liability under these sections.

**Table of Contents**

**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: August 12, 2014

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

President and Chief Executive Officer