Ignyta, Inc.
Form 10-Q
November 07, 2016
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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 September 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-36344

Ignyta, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-3174872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4545 Towne Centre Court, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 255-5959

(Registrant s telephone number, including area code)

11111 Flintkote Avenue, San Diego, CA 92121

(Former name, former address and former fiscal year, if changed since last report)

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

As of October 31, 2016, the registrant had 41,652,863 shares of common stock ($0.0001 per share par value) outstanding.

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IGNYTA, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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PART I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Ignyta, Inc.

Condensed Balance Sheets

(In thousands, except share data)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 23,469	$ 46,383
Short-term investment securities	98,944	85,420
Prepaid expenses and other current assets	6,872	4,191
Total current assets	129,285	135,994
Long-term investment securities	30,070	40,346
Property and equipment, net	30,087	18,764
Other long-term assets	343	410
Total assets	$ 189,785	$ 195,514
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,128	$ 3,828
Accrued expenses and other liabilities	11,641	13,860
Current portion of long-term debt	188	6,856
Total current liabilities	13,957	24,544
Term loan, net of current portion and discount	29,352	22,821
Other long-term liabilities	25,687	12,164
Total liabilities	68,996	59,529
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par; 10,000,000 shares authorized; no shares issued or outstanding		
Common stock, $0.0001 par; 150,000,000 shares authorized; 41,652,863 and	4	3

32,339,081 shares issued and outstanding at September 30, 2016, and December 31, 2015, respectively		
Additional paid-in capital	344,251	284,252
Accumulated other comprehensive loss	(15)	(249)
Accumulated deficit	(223,451)	(148,021)
Total stockholders equity	120,789	135,985
Total liabilities and stockholders equity	$ 189,785	$ 195,514

See the accompanying notes to these unaudited condensed financial statements.

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Ignyta, Inc.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

(**Unaudited**)

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 16,626	$ 10,432	$ 56,425	$ 39,444
General and administrative	6,145	3,857	16,871	10,478
Total operating expenses	22,771	14,289	73,296	49,922
Loss from operations	(22,771)	(14,289)	(73,296)	(49,922)
Other income (expense):				
Loss on debt extinguishment			(696)	
Interest expense	(814)	(580)	(2,404)	(1,785)
Other income (expense)	296	248	966	460
Total other income (expense), net	(518)	(332)	(2,134)	(1,325)
Net loss	$ (23,289)	$ (14,621)	$ (75,430)	$ (51,247)
Comprehensive loss:				
Net loss	$ (23,289)	$ (14,621)	$ (75,430)	$ (51,247)
Net unrealized gain (loss) on investment securities	(78)	63	234	42
Comprehensive loss	$ (23,367)	$ (14,558)	$ (75,196)	$ (51,205)
Net loss per share:				
Net loss per share basic and diluted	$ (0.56)	$ (0.49)	$ (2.02)	$ (2.02)
Weighted average shares outstanding basic and diluted	41,652	29,601	37,413	25,365

See the accompanying notes to these unaudited condensed financial statements.

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Ignyta, Inc.

Condensed Statements of Cash Flows

(In thousands)

(**Unaudited**)

	Nine months ended September 30,	
	2016	**2015**
Operating activities:		
Net loss	$ (75,430)	$ (51,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on debt extinguishment	696	
In-process research and development charge associated with asset acquisition		11,880
Stock-based compensation	5,436	3,431
Depreciation and amortization of property and equipment	2,735	1,255
Amortization of premium on investment securities, net of accretion of discounts	611	1,115
Amortization of non-cash financing costs	428	404
Other	(129)	
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	(2,040)	(2,141)
Accounts payable	(1,700)	2,271
Accrued expenses and other liabilities	(2,030)	1,641
Net cash used in operating activities	(71,423)	(31,391)
Investing activities:		
Purchases of investment securities	(123,857)	(116,908)
Maturities and sales of investment securities	120,291	80,260
Purchases of property and equipment	(1,760)	(2,562)
Net cash used in investing activities	(5,326)	(39,210)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	53,892	111,589
Proceeds from borrowings under term loan facility	17,116	10,000
Repayments of borrowings under term loan facility	(17,438)	
Proceeds from exercise of stock options	400	361
Repayments under other long-term obligations	(135)	(128)
Net cash provided by financing activities	53,835	121,822
Net change in cash and cash equivalents	(22,914)	51,221
Cash and cash equivalents at beginning of period	46,383	6,346

Cash and cash equivalents at end of period	$ 23,469	$ 57,567
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,976	$ 1,368
Noncash investing and financing activities:		
Amounts capitalized under build-to-suit lease transaction	$ 11,802	$
Interest capitalized during construction period for build-to-suit lease transaction	$ 1,073	$
Final payment obligation to Lenders recorded as debt discount (see note 6)	$ 1,600	$
Unrealized gain on investment securities	$ 234	$ 42

See the accompanying notes to these unaudited condensed financial statements.

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Ignyta, Inc.

Notes to Unaudited Condensed Financial Statements

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization and Nature of Operations

Ignyta, Inc. (Ignyta or the Company) is incorporated in the state of Delaware and was founded in 2011 (with the name NexDx, Inc.). The Company changed its name to Ignyta, Inc. on October 8, 2012. The Company is focused on precision medicine in oncology. Its goal is not just to shrink tumors, but to eradicate residual disease the source of cancer relapse and recurrence in precisely defined patient populations. The Company is pursuing an integrated therapeutic (Rx) and companion diagnostic (Dx) strategy for treating patients with cancer. Its Rx efforts are focused on in-licensing or acquiring, then developing and commercializing molecularly targeted therapies that, sequentially or in combination, are foundational for eradicating residual disease. Its Dx efforts aim to pair these product candidates with biomarker-based companion diagnostics that are designed to precisely identify, at the molecular level, the patients who are most likely to benefit from the therapies it develops.

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

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

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, the instructions to Form 10-Q and related SEC rules and regulations. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

In management s opinion, the accompanying unaudited condensed 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 condensed financial statements should be read in conjunction with the Company s audited financial

statements and footnotes included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the SEC.

Liquidity

The Company had negative cash flow from operations of approximately $71.4 million during the first nine months of 2016 and, as of September 30, 2016, had an accumulated deficit of approximately $223.5 million. The Company is focused primarily on its development programs, and management believes such activities will result in the continued incurrence of significant research and development and other expenses related to those programs. The Company expects that it will need additional capital to further fund development of, and seek regulatory approvals for, its product candidates, and begin to commercialize any approved products. If the clinical trials for any of the Company s products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of its product candidates, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash on hand and through additional financing from existing and prospective investors. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or to its stockholders.

As of September 30, 2016, the Company had cash, cash equivalents and investment securities totaling $152.5 million. While the Company expects that its existing cash, cash equivalents and investment securities will enable it to fund its operations and capital expenditure requirements for at least the next twelve months, having insufficient funds may require the Company to delay, reduce, limit or terminate some or all of its development programs or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market on its own.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Cash and Cash Equivalents

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

Investment Securities

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

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

Fair Value of Financial Instruments

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

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

of the following categories:

Level 1: Quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

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

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Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents, investment securities and the term loan. The Company maintains its cash and cash equivalents with financial institutions in amounts that typically exceed the amount of federal insurance provided on such deposits. With respect to the Company s investment securities and its term loan, the primary exposure to market risk is the risk that prevailing interest rates may change, causing the value of these investments and its term loan to fluctuate. The Company has not experienced any significant losses on its cash, cash equivalents, investments or its term loan The Company s credit risk exposure is up to the extent of the value of its cash and investments recorded on the Company s balance sheet.

Cash is invested in accordance with a policy approved by the Company s board of directors which specifies the categories, allocations, and ratings of securities that the Company may consider for investment. Based on discussions with the Company s treasury managers and a review of the Company s holdings, management does not believe that the Company s cash, cash equivalents and investment securities have significant risk of default or illiquidity.

Clinical Trial and Pre-Clinical Study Accruals

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

Research and Development

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

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

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

Stock-Based Compensation

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

Net Loss per Share

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

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The calculations of net loss per share excluded potentially dilutive securities (consisting of outstanding options, warrants, restricted stock and restricted stock units) of approximately 5.6 million and 5.0 million shares as of September 30, 2016 and 2015, respectively.

Reclassifications

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

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amended previous guidance on employee share-based payment accounting. This update involves several aspects of the accounting for share-based payment transactions, including income tax effects, forfeitures and classifications on the statement of cash flows. This guidance is effective for the Company s fiscal year beginning January 1, 2017. The Company believes that this guidance will not have a material impact on its consolidated financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases. A lessee will be required to recognize on the balance sheet the assets and liabilities for leases with lease terms of more than 12 months. The new standard is effective for public companies for the Company s fiscal year beginning January 1, 2019, and early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related financial statement disclosures.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities*. This update addresses certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The new standard is effective for the Company s fiscal year beginning January 1, 2018. The Company is evaluating the impact of this guidance on its financial statements and related financial statement disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. The amendment requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management s plan to alleviate these doubts are required. This update will become effective for the Company s fiscal year beginning January 1, 2017. The Company believes that this guidance will not have a material impact on its consolidated financial position or results of operations upon adoption.

3. INVESTMENT SECURITIES

Following is a summary of the available-for-sale investment securities held by the Company as of the dates below (*in thousands*):

	As of September 30, 2016			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Market Value**
Available-for-sale investment securities:				
Commercial paper	$ 17,763	$	$	$ 17,763
Corporate debt securities	60,676	21	(39)	60,658
U.S. government and agency obligations	50,591	11	(9)	50,593
Total	$ 129,030	$ 32	$ (48)	$ 129,014

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	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
Commercial paper	$ 7,992	$	$	$ 7,992
Corporate debt securities	94,959	3	(180)	94,782
U.S. government and agency obligations	23,064		(72)	22,992
Total	$ 126,015	$ 3	$ (252)	$ 125,766

None of the Company s available-for-sale investment securities held at September 30, 2016, had maturity dates of more than 24 months. The Company determines the appropriate designation of investments at the time of purchase and reevaluates such designation as of each balance sheet date. Investment securities classified as short-term investments have maturity dates of less than one year from the balance sheet date, while securities classified as long-term investments have maturity dates of greater than one year from the balance sheet date. The cost of securities sold is based on the specific identification method. Amortization of premiums, accretion of discounts, interest, dividend income, and realized gains and losses are included in investment income.

None of the Company s available-for-sale investment securities were in a material unrealized loss position at September 30, 2016. The Company reviewed its investment holdings as of September 30, 2016, and determined that its unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that no securities have been in an unrealized loss position for twelve months or more. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale investment securities. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented.

4. FAIR VALUE MEASUREMENTS

The Company holds investment securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its investment 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 s financial assets measured at fair value on a recurring basis were as follows (*in thousands*):

	As of September 30, 2016				As of December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 23,469	$	$	$ 23,469	$ 46,383	$	$	$ 46,383
Investment securities:								

Commercial paper		17,763		17,763		7,992	7,992
Corporate debt securities		60,658		60,658		94,782	94,782
U.S. government and agency obligations	50,593			50,593	22,992		22,992
Total assets at fair value	$ 74,062	$ 78,421	$	$ 152,483	$ 69,375	$ 102,774	$ $ 172,149

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5. BALANCE SHEET DETAILS

Property and Equipment

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

	As of September 30, 2016	As of December 31, 2015
Lab and manufacturing equipment	$ 7,663	$ 6,941
Leasehold improvements	2,355	2,349
Computer and office equipment	1,349	1,145
Property and equipment at cost	11,367	10,435
Less accumulated depreciation and amortization	(5,155)	(2,671)
Subtotal	6,212	7,764
Construction in process (see build-to-suit property below)	23,875	11,000
Property and equipment, net	$ 30,087	$ 18,764

Accrued Expenses and Other Liabilities

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

	As of September 30, 2016	As of December 31, 2015
Clinical trial services fees and related costs	$ 3,198	$ 5,766
Research and development services	3,600	1,763
Personnel and related costs	2,492	3,844
Other liabilities	2,351	2,487
Total	$ 11,641	$ 13,860

Other Long-Term Liabilities

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

	As of September 30,	As of December 31,

	2016	2015
Leased facility financing obligation (see below)	$ 23,875	$ 11,000
Final loan fee obligation to lender (see note 6)	1,600	930
Other	212	234
Total	$ 25,687	$ 12,164

Build-to-Suit Property and Leased Facility Financing Obligation

In October 2015, the Company entered into an agreement for the lease of laboratory and office space on a build-to-suit basis for its new headquarters location in San Diego, California. The buildings that house the leased space as well as the space leased by the Company underwent a significant renovation, which was completed in October 2016. Based on the terms of the lease agreement and authoritative literature, the Company was determined to bear substantially all of the construction-related risks during the construction period and was deemed the owner of the building for accounting purposes during the construction period. As a result, the Company s balance sheets at September 30, 2016, and December 31, 2015, included a fixed asset (construction in process) and a corresponding leased facility financing obligation of $23.9 million and $11.0 million, respectively, reflecting the estimated replacement cost of these buildings at lease inception and the accumulated build-out costs incurred subsequent to lease inception.

At the time the Company took possession of the properties in the fourth quarter of 2016, it determined that it had transferred the risks of ownership back to the owner of the properties. As such, the Company satisfied the requirements for sale-leaseback accounting treatment and it will derecognize both the building assets and the related liability in October 2016.

6. TERM LOAN FACILITY

In June 2016, the Company entered into a term loan facility with Silicon Valley Bank, as collateral agent (SVB), and Oxford Finance LLC (Oxford and collectively with SVB, the Lenders). Under the loan facility, the Company received initial funding of $32.0 million, substantially all of which was used to repay the Company s prior loan with SVB. The Company considered

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authoritative literature which states that modifications or exchanges are considered extinguishments with gains or losses recognized in current earnings if the terms of the new debt and original instrument are substantially different. The Company determined that for SVB s portion of the new facility, the terms are not substantially different from the prior loan and should be accounted for as a debt modification with previously deferred financing costs amortized as an adjustment of interest expense over the remaining term of the modified debt using the interest method. The Company determined that the portion of the old facility with SVB that was not assumed by SVB under the new facility should be accounted for as a debt extinguishment with fees paid to the lender and previously deferred financing costs included in the calculation of loss on debt extinguishment. The Company recorded a loss on debt extinguishment of $0.7 million during the second quarter of fiscal 2016.

Borrowings under the new facility will bear interest at a rate equal to the Prime Rate plus 4.35% (7.85% at September 30, 2016) and have interest only payments for twenty-four months, followed by a principal amortization period of thirty-six months. The interest only period will be extended, however, by an additional six months in the event of either (i) the Company raising sufficient capital or (ii) the Company receiving certain clinical trial data. In the event that the interest only period is extended, the principal amortization period will be reduced to thirty months.

Upon the maturity date, the Company must make a final lump-sum payment of 5.0% of the full amount of the loan funded ($1.6 million). The fair value of the final payment has been recorded as a debt discount which is being amortized to interest expense over the term of the loan agreement. The Company may elect to prepay all amounts owed prior to the maturity date provided that a prepayment fee is also paid, equal to 2% of the amount prepaid if the prepayment occurs on or prior to June 30, 2017, or 1% of the amount prepaid if the prepayment occurs thereafter. Under the facility, the Company also has a conditional option to receive an additional $10.0 million loan tranche (the Second Tranche). The Second Tranche may be drawn down by the Company at any time from April 7, 2017, to August 31, 2017, provided that the Company has received certain clinical trial data and subject to other customary conditions for funding.

In connection with this facility, the Company issued warrants to the Lenders to purchase an aggregate of approximately 94,116 shares of its common stock. The warrants are exercisable immediately, have a per-share exercise price of $5.10 and have a term of seven years. If the Company draws down the Second Tranche, at that time it will issue to the Lenders additional warrants which will be exercisable immediately and have a term of seven years. Those warrants will be exercisable for an aggregate number of shares equal to $150,000 (which is 1.5% of the principal amount of the Second Tranche) divided by the lower of (a) the trailing 10-day average of the closing price of the Company s common stock on the Nasdaq Capital Market prior to the funding date of the Second Tranche and (b) the closing price of the Company s common stock on the Nasdaq Capital Market on the funding date of the Second Tranche, at an exercise price equal to such divisor. The warrants qualify for equity classification and the fair value of the warrants has been recorded as a debt discount which is being amortized to interest expense over the term of the loan agreement.

Future minimum principal payments of approximately $0.9 million commence in July 2018 and are due monthly through June 2021 as follows (*in thousands*):

Year ending December 31,	*Minimum Principal Payments*
2016 (3 months) and 2017	$
2018	5,333

2019	10,667
2020	10,667
After	5,333
Total	$ 32,000

The Company is bound by certain affirmative and negative covenants setting forth actions that it must and must not take during the term of the loan agreement. Under the loan agreement, the Company must also maintain the majority of its cash in accounts at SVB. Upon the occurrence of an event of default, subject to cure periods for certain events of default, all amounts owed by the Company thereunder shall begin to bear interest at a rate that is 3% higher than the rate that is otherwise applicable and may be declared immediately due and payable by the Lenders. The Company has granted SVB, as collateral agent for the ratable benefit of the Lenders, a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed under this agreement. The Company has also agreed not to encumber any of its intellectual property without the required lenders prior written consent.

7. ASSET ACQUISITION

On March 17, 2015, under the terms of an asset purchase agreement with Cephalon, Inc. (Cephalon), an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. (Teva), the Company acquired certain assets relating to certain oncology development programs, including Cephalon s right, title and interest in and to certain intellectual property, compounds, products,

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contracts, records, data and development supplies related to the Company s RXDX-105 and RXDX-106 programs (the Purchased Assets), and assumed certain related commitments. As consideration for the Purchased Assets, the Company issued to Cephalon 1,500,000 shares of common stock and assumed certain other third-party obligations. The Company did not acquire any marketable products, established customer or employee bases, or any established business, management, operational or resource management processes. Accordingly, the Company recorded this transaction as an asset purchase as opposed to a business combination. The acquired assets were in various stages of drug development, ranging from preclinical stage to Phase 1 clinical trials, and the development plans were still being formulated and were not complete as of the date of acquisition. As the success of the Company s commercialization of these acquired compounds was uncertain and the assets in question had no alternative future uses, the Company recorded an in-process research and development charge of approximately $11.9 million during the first quarter of 2015 related to this transaction based on the value of the net assets exchanged for the Teva assets. Under the provisions of the asset purchase agreement, the Company also paid approximately $0.9 million to Cephalon for drug development supplies, which was included in research and development expenses during the first quarter of 2015.

8. LICENSE AGREEMENTS

Entrectinib

The Company entered into a license agreement with Nerviano Medical Sciences S.r.l. (NMS) on October 10, 2013, which was amended on October 25, 2013, became effective on November 6, 2013, and was amended December 12, 2014. The agreement grants the Company exclusive global rights to develop and commercialize entrectinib. The Company s development rights under the license agreement are exclusive for the term of the agreement with respect to entrectinib and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with activity against the target proteins of entrectinib, and include the right to grant sublicenses. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on entrectinib at its expense.

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

Taladegib

On November 6, 2015, the Company entered into a license, development and commercialization agreement with Eli Lilly and Company (Lilly) under which the Company received exclusive, global rights to develop and commercialize pharmaceutical products under the licensed technology (Licensed Products), including Lilly s product candidate taladegib. Taladegib is an orally bioavailable, small molecule hedgehog/smoothened antagonist that has achieved clinical proof of concept and a recommended Phase 2 dose in a Phase 1 dose escalation trial. The Company granted back to Lilly an exclusive license to develop and commercialize pharmaceutical products comprising taladegib in

combination with certain other molecules (Combination Products). The Company also licensed the exclusive worldwide rights to the topical formulation of taladegib, which is a late preclinical development program for the potential treatment of patients with superficial and nodular basal cell carcinoma. In February 2016, the Company ceased all development activities relating to the topical taladegib program. Both parties rights under the agreement include the right to grant sublicenses. The Company is obligated under the agreement to use commercially reasonable efforts to develop and commercialize Licensed Products, at its expense. Both parties have a right to terminate the agreement if the other party enters bankruptcy, upon an uncured breach by the other party or if the other party challenges its patents relating to the licensed technology. The Company has been in discussions with Lilly regarding the optimal path forward for taladegib in the context of its pipeline priorities. In connection with these discussions Lilly has indicated that it believes that the Company may not have satisfied certain of its obligations to Lilly under the license agreement, but Lilly has also indicated an interest in achieving an amicable resolution with respect to this issue and the parties are continuing discussions consistent with this desire.

The terms of the license agreement provided for an up-front payment to Lilly of $2.0 million, plus the issuance to Lilly in a private placement of 1,213,000 shares of the Company s common stock. The Company included the up-front payment in research and development costs and recorded the value of the shares issued as equity in the fourth quarter of 2015. The license agreement also requires that the Company makes development and sales milestone payments to Lilly of up to $38.0 million. In addition, a portion of the $30.0 million in gross proceeds provided to the Company by Lilly in a concurrent private placement of the Company s common stock to Lilly (in November 2015) has been earmarked for development of the product and payment of milestone obligations under the

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license agreement. When and if commercial sales of Licensed Products begin, the Company will be obligated to pay Lilly a mid-single digit royalty of net sales of Licensed Products. When and if commercial sales of Combination Products begin, Lilly will be obligated to pay the Company a mid-single digit royalty of net sales of Combination Products. Both parties royalty obligations are subject to standard provisions for royalty offsets to the extent a party is required to obtain any rights from third parties to commercialize the applicable products, or in the event of loss of exclusivity or generic competition.

RXDX-105 and RXDX-106

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

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

9. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases office and laboratory space and certain lab equipment under operating leases that expire through 2026. Certain of the facility leases contain periodic rent increases that result in the Company recording deferred rent over the term of these leases. Future minimum lease payments under the non-cancellable portion of operating leases totaled $25.3 million as of September 30, 2016.

The Company has also entered into capital lease arrangements for the purchase of certain lab equipment. Future minimum lease payments under the Company s capital lease obligations totaled $0.2 million as of September 30, 2016.

Clinical Trial Study Agreement Commitments

The Company has entered into agreements with several contract research organizations for clinical studies to be conducted both within and outside the U.S. for its product candidates. The total contracted cost under these arrangements totaled approximately $78.7 million as of September 30, 2016, of which approximately $29.7 million has been incurred to date. These agreements run through various dates, with the longest term expected to run through 2020. These contracts can be terminated at any time with no more than 60 days notice, at which point the Company would be obligated to pay for costs incurred though the termination date.

Other matters

Although the Company is currently not a party to any material legal proceedings, in the normal course of business, the Company has been, and will likely continue to be, subject to claims, administrative proceedings or litigation incidental to its business that are either judged to be not material or that arise in the ordinary course of business from time to time, such as claims related to customer disputes, employment practices, wage and hour disputes, professional liability, licensure restrictions or denials, and patent infringement. Responding to such matters, regardless of whether they have merit, can be expensive and disruptive to normal business operations. Due to the uncertainties inherent in legal proceedings and litigation, the Company is not able to predict the timing or outcome of these matters. The Company could in the future incur judgments or enter into settlements of claims that could have an adverse effect on its results of operations in any particular period.

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10. STOCKHOLDERS EQUITY

Authorized Shares

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

Stock Offerings

In May 2016, the Company completed a public offering of an aggregate of 9,200,000 shares of its common stock for net proceeds of approximately $53.9 million (net of transaction costs of approximately $3.6 million).

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

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

At-The-Market Issuance Sales Agreement

In December 2015, the Company entered into an at-the-market issuance sales agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) pursuant to which the Company may issue and sell shares of its common stock from time to time, at the Company s option, through Cantor as its sales agent. The Company is not obligated to make any sales of its common stock under the Sales Agreement, and it may terminate its agreement with Cantor at any time. Any shares sold will be sold pursuant to an effective shelf registration statement on Form S-3. The Company will pay Cantor a commission of 3.0% of the gross proceeds of any such sales. The Company has reserved up to $33.0 million under its shelf registration statement for shares that may be issued under the Sales Agreement. Through September 30, 2016, the Company has not made any sales of shares in connection with this arrangement.

Common Stock Warrants

Warrants to purchase an aggregate of 153,472 shares of the Company s common stock were outstanding at September 30, 2016. These warrants have a weighted average exercise price of $5.75 per share and expire at various dates through June 2023.

11. EQUITY AWARDS

Equity Incentive Plans

The Company may issue equity awards to either employees or non-employees under its Amended and Restated 2014 Incentive Award Plan (the 2014 Plan). The 2014 Plan provides for the issuance of up to 6,000,000 shares, plus one additional share for each option share granted under the Company s 2011 Incentive Award Plan (the 2011 Plan) that expires, is forfeited or is settled in cash subsequent to June 11, 2014. Options granted under the 2014 Plan may be subject to vesting and expire no more than ten years from their date of grant.

The Company has outstanding equity awards that were granted under its 2011 Plan, its 2014 Employment Inducement Incentive Award Plan and its 2015 Employment Inducement Incentive Award Plan. No additional equity grants may be made by the Company under any of these predecessor plans.

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

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value (000 s)
Balance at December 31, 2015	5,250,941	$ 9.16		
Granted	1,175,141	$ 8.37		
Exercised	(113,782)	$ 3.51		
Forfeited and expired	(1,089,509)	$ 10.15		
Balance at September 30, 2016	5,222,791	$ 8.90	8.3	$ 1,045
Exercisable at September 30, 2016	2,016,716	$ 7.64	8.3	$ 1,037

As of September 30, 2016, an aggregate of 3,488,069 shares remain available for grant under the Company s equity incentive plans.

Fair Value of Equity Awards

The Company utilizes the Black Scholes option pricing model to value its equity awards. The fair value of options granted during the first nine months of 2016 and 2015 was $5.35 and $7.03 per share, respectively, and was estimated using the following weighted-average assumptions:

	Fiscal 2016	**Fiscal 2015**
Expected life of option	6.0 years	6.2 years
Volatility	73%	68%
Risk free interest rate	1.4%	1.7%
Dividend yield	%	%

Stock-Based Compensation

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

	Three months ended September 30,		**Nine months ended September 30,**	
	2016	**2015**	**2016**	**2015**
Included in research and development	$ 992	$ 651	$ 2,613	$ 1,568
Included in general and administrative	1,044	676	2,823	1,863

Total	$ 2,036	$ 1,327	$ 5,436	$ 3,431

As of September 30, 2016, unrecognized stock-based compensation expense related to unvested stock-based awards totaled $16.6 million and is expected to be recognized over a weighted-average period of 2.7 years.

Restricted Stock Units

Under the provisions of its equity incentive plans, the Company may grant restricted stock units (RSUs) to employees and members of its board of directors. During the nine months ended September 30, 2016, the Company issued a total of 206,880 RSUs to members of its management team. As of September 30, 2016, a total of 238,480 RSUs were outstanding and subject to future vesting at various dates through January 2021.

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

The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2015, and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2015. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption Risk Factors in the Annual Report on Form 10-K for the year ended December 31, 2015, and the caption Risk Factors in this Quarterly Report on Form 10-Q, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

On October 31, 2013, we merged with and into IGAS Acquisition Corp., a wholly owned subsidiary of Ignyta, Inc., a Nevada corporation previously named Infinity Oil & Gas Company, or Parent, formerly a shell company under applicable rules of the Securities and Exchange Commission, or the SEC. We survived the merger as a wholly owned subsidiary of Parent. In the merger, Parent acquired our business and continued our business operations. The merger is accounted for as a reverse merger and recapitalization, with us as the acquirer and Parent as the acquired company for financial reporting purposes. As a result, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the merger are ours and are recorded at our historical cost basis, and the consolidated financial statements after completion of the merger include the assets and liabilities of Parent and us, the historical operations of us and the operations of the combined enterprise of Parent and us from and after the closing date of the merger. As a result of the accounting treatment of the merger and the change in Parent s business and operations from a shell company to a precision oncology biotechnology company, a discussion of the past financial results of the shell company is not pertinent or material, and the following discussion and analysis of our financial condition and results of operations are based on our financial statements. On June 12, 2014, Parent merged with and into us, with us surviving the merger and changing our name to Ignyta, Inc. This merger had no material impact on the accounting of the company. Unless the context indicates or otherwise requires, the terms we, us, our and our company refer to (i) Parent and us, its consolidated subsidiary, for discussions relating to periods before and through June 12, 2014, and (ii) us, the surviving company to the June 12, 2014, merger, for discussions relating to periods after June 12, 2014.

Overview

We are a leading precision oncology biotechnology company. Our goal is not just to shrink tumors, but to eradicate residual disease the source of cancer relapse and recurrence in precisely defined patient populations. We are pursuing an integrated therapeutic, or Rx, and companion diagnostic, or Dx, strategy for treating patients with cancer. Our Rx efforts are focused on in-licensing or acquiring, then developing and commercializing molecularly targeted therapies that, sequentially or in combination, are foundational for eradicating residual disease. Our Dx efforts aim to pair these product candidates with biomarker-based companion diagnostics that are designed to precisely identify, at the molecular level, the patients who are most likely to benefit from the therapies we develop.

Our current pipeline includes the following compounds:

- entrectinib, formerly called RXDX-101, an orally bioavailable, small molecule tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in a Phase 2 clinical study and two Phase 1 clinical studies in molecularly defined

adult patient populations for the treatment of solid tumors, and one Phase 1/1b clinical study in pediatric patients with advanced solid tumor malignancies;

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

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

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

We acquired exclusive global development and commercialization rights to entrectinib under a license agreement with Nerviano Medical Sciences S.r.l., or NMS, that became effective in November 2013; we acquired exclusive, global development and commercialization rights to taladegib under a license agreement with Eli Lilly and Company, or Lilly, in November 2015; and we acquired our RXDX-105 and RXDX-106 development programs in an asset purchase transaction with Cephalon, Inc., an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., or Teva, in March 2015.

In May 2016, we determined to prioritize our resources and development efforts on our lead product candidate, entrectinib. In connection with this, we determined to discontinue our Spark discovery-stage program and are in discussions with Lilly regarding the optimal path forward for taladegib in the context of our pipeline priorities. In connection with these discussions Lilly has indicated

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that it believes that we may not have satisfied certain of our obligations to Lilly under the license agreement, but Lilly has also indicated an interest in achieving an amicable resolution with respect to this issue and the parties are continuing discussions consistent with this desire.

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

Financial Operations Overview

Revenue

To date, we have not generated any material revenue from services, product sales or otherwise. In the future, we expect that we will seek to generate revenue primarily from product sales, but we may also seek to generate revenue from research funding, milestone payments and royalties on future product sales in connection with any out-license or other strategic relationships we may establish.

Research and Development Expenses

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

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

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

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

Research and development activities are central to our business model. Our research and development programs that we expect will be our focus in the immediate future consist of the development of our ongoing entrectinib and other development programs. Since product candidates in later stages of development generally have higher development costs than those in earlier stages of development, we expect research and development costs relating to each of those programs to increase significantly for the foreseeable future as those programs progress. However, the successful development of any of our product candidates, or any others we may seek to pursue, is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development for our programs, or whether any of our product candidates will reach successful commercialization. We are also unable to predict when, if ever, any net cash inflows will commence from any of the product candidates we currently or may in the future pursue. This lack of predictability is due to the numerous risks and uncertainties associated with developing medicines, many of which, such as our ability to obtain approvals to market and sell those medicines from the U.S. Food and Drug Administration, or the FDA, and other applicable regulatory authorities, are beyond our control, including the uncertainty of:

- establishing an appropriate safety profile with toxicology studies and an acceptable dosing form to submit an IND to the FDA or comparable applications to foreign regulatory authorities;

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

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successful demonstration of an acceptable safety profile with clinically meaningful efficacy to achieve a favorable benefit/risk profile sufficient to obtain regulatory approval in one or more countries;

a product profile, including safety and efficacy, that is sufficiently differentiated, adequately reimbursed and commercially competitive;

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

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

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

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

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

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

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

General and Administrative Expenses

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

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

Critical Accounting Policies and Estimates

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

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, please see Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have not been any material changes to our critical accounting policies since December 31, 2015.

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amended previous guidance on employee share-based payment accounting. This update involves several aspects of the accounting for share-based payment transactions, including income tax effects, forfeitures and classifications on the statement of cash flows. This guidance is effective for the Company s fiscal year beginning January 1, 2017. The Company believes that this guidance will not have a material impact on its consolidated financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases.

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

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities*. This update addresses certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments. The new standard is effective for the Company s fiscal year beginning January 1, 2018. The Company is evaluating the impact of this guidance on its financial statements and related financial statement disclosures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. The amendment requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management s plan to alleviate these doubts are required. This update will become effective for the Company s fiscal year beginning January 1, 2017. The Company believes that this guidance will not have a material impact on its consolidated financial position or results of operations upon adoption.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015, together with the changes in those items in dollars (*in thousands*) and as a percentage:

	Three months ended September 30,		Dollar	Percentage
	2016	2015	Change	Change
Operating expenses:				
Research and development	$ 16,626	$ 10,432	$ 6,194	59%
General and administrative	6,145	3,857	2,288	59%
Total operating expenses	22,771	14,289	8,482	59%
Loss from operations	(22,771)	(14,289)	(8,482)	59%
Other income (expense), net	(518)	(332)	(186)	56%
Net loss	$ (23,289)	$ (14,621)	$ (8,668)	59%

Research and Development Expense. Research and development expenses increased in the three months ended September 30, 2016 as compared to the same period in 2015 by $6.2 million, or 59%. This increase was primarily due to the $4.3 million increase in the external development costs associated with our entrectinib, taladegib and other product candidates. Salaries, share-based compensation expense and other personnel-related costs also increased as our research and development headcount increased year-over-year.

General and Administrative Expense. General and administrative expenses increased by approximately $2.3 million for the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, an increase of 59%. This increase was driven by higher personnel and share-based compensation costs. Additionally, we incurred higher facilities related expenses resulting from the increase of our leased facilities space, and increases in consulting fees and depreciation expense.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015, together with the changes in those items in dollars (*in thousands*) and as a percentage:

	Nine months ended September 30, 2016	2015	Dollar Change	Percentage Change
Operating expenses:				
Research and development	$ 56,425	$ 39,444	$ 16,981	43%
General and administrative	16,871	10,478	6,393	61%
Total operating expenses	73,296	49,922	23,374	47%
Loss from operations	(73,296)	(49,922)	(23,374)	47%
Other income (expense), net	(2,134)	(1,325)	(809)	61%
Net loss	$ (75,430)	$ (51,247)	$ (24,183)	47%

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Research and Development Expense. Research and development expenses increased during the nine months ended September 30, 2016, as compared to the same period in 2015. During the nine months ended September 30, 2015, we recorded an in-process research and development charge of approximately $11.9 million representing the net value of the assets exchanged for the intellectual property assets acquired from Teva, as well as transaction and drug product related costs of $1.2 million. Excluding these costs, research and development costs would have increased in the nine months ended September 30, 2016 as compared to the same period in 2015 by $30.1 million, or 114%, primarily due to the $18.9 million increase in the external development costs associated with our entrectinib, taladegib and other product candidates. Salaries, share-based compensation expense and other personnel-related costs also increased as our research and development headcount increased year-over-year.

General and Administrative Expense. General and administrative expenses increased by approximately $6.4 million for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015, an increase of 61%. This increase was driven by higher personnel and share-based compensation costs. Additionally, we incurred higher facilities related expenses resulting from the increase of our leased facilities space, as well as increases in consulting fees and depreciation expense.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, and through September 30, 2016, we have raised an aggregate of approximately $352.2 million to fund our operations, of which approximately $57.5 million was received from our issuance and sale of our common stock in an underwritten public offering in May 2016, approximately $30.0 million was received from our issuance and sale of our common stock to Lilly in November 2015, approximately $75.0 million was received from our issuance and sale of our common stock in an underwritten public offering in June 2015, approximately $41.6 million was raised through our issuance and sale of our common stock in a registered direct offering in March 2015, approximately $55.2 million was received from our issuance and sale of our common stock in an underwritten public offering in March 2014, approximately $54.1 million was received from our issuance and sale of our common stock in two private placements in November 2013, approximately $32.0 million was received from the incurrence of indebtedness under our loan agreement with Silicon Valley Bank, or SVB, and Oxford Finance LLC, or Oxford, and collectively with SVB, the Lenders, and approximately $6.0 million was received from our issuance and sale of our preferred stock. We had also received a small amount of funding from our issuance of common stock to our founders in August and September 2011, and from our issuance of common stock upon the exercise from time to time of stock options.

Public Offerings. In May 2016, June 2015 and March 2014, we issued an aggregate of 19,517,464 shares of our common stock in underwritten public offerings. All of the shares issued in the May 2016 offering were sold at a purchase price per share of $6.25, all of the shares issued in the June 2015 offering were sold at a purchase price per share of $17.50, and all of the shares issued in the March 2014 offering were sold at a purchase price per share of $9.15. The offerings generated aggregate gross proceeds of approximately $187.7 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately $175.5 million.

Private Placements. In November 2015, we issued and sold 1,500,000 shares of common stock to Lilly at a purchase price per share of $20.00, for aggregate gross and net proceeds of $30.0 million (the costs associated with this transaction being negligible). In November 2013, we entered into securities purchase agreements with accredited investors providing for the issuance and sale to such investors of an aggregate of 9,010,238 shares of our common stock in private placement transactions. All of the shares issued in the November 2013 private placements were sold at

a purchase price per share of $6.00, for aggregate gross proceeds of approximately $54.1 million and aggregate net proceeds, after deducting placement agent and other offering fees and expenses, of approximately $51.0 million.

Registered Direct Offering. In March 2015, we issued an aggregate of 4,158,750 shares of our common stock in a registered direct offering. The shares issued in the offering were sold at a purchase price per share of $10.00 per share, for aggregate gross proceeds of approximately $41.6 million and aggregate net proceeds, after deducting offering fees and expenses, of approximately $41.4 million.

Loan Agreement with SVB and Oxford. In June 2016, we entered into a loan agreement with the Lenders under which we incurred $32.0 million of indebtedness, substantially all of which was used to repay our then-existing loan with SVB. We have a conditional option to borrow an additional $10.0 million tranche under this loan facility upon satisfaction of certain specified criteria. We are required to pay interest on the outstanding borrowings under this loan agreement at an interest rate equal to the Prime Rate plus 4.35% (7.85% at September 30, 2016). Monthly principal payments of approximately $0.9 million commence in July 2018 and are due through June 2021. Further, the terms of the loan agreement require that we make a final lump-sum payment at loan maturity equal to 5.0% of the principal amount of the loans funded thereunder. We may elect to prepay all amounts owed under either or both of the

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loan tranches prior to the maturity date, provided that we pay a prepayment fee. The prepayment fee will be equal to 2.0% of the amount prepaid if the prepayment occurs on or prior to June 30, 2017, or 1% of the amount prepaid if the prepayment occurs thereafter. Pursuant to the 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. Under the loan agreement, we must also maintain the majority of our cash in accounts at SVB. Upon the occurrence of an event of default under the loan agreement, subject to cure periods for certain events of default, all amounts owed by us thereunder shall begin to bear interest at a rate that is 3% higher than the rate that is otherwise applicable and may be declared immediately due and payable to the Lenders. We have granted SVB, as collateral agent for the ratable benefit of the Lenders, a security interest in substantially all of our personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed to the Lenders under the loan agreement. We have also agreed not to encumber any of our intellectual property without the required lenders prior written consent.

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

Cash Flows

The following table provides information regarding our cash flows during the nine months ended September 30, 2016 and 2015 (*in thousands*):

	Nine months ended September 30,	
	2016	2015
Net cash used in operating activities	$ (71,423)	$ (31,391)
Net cash used in investing activities	(5,326)	(39,210)
Net cash provided by financing activities	53,835	121,822
Net (decrease)/increase in cash and cash equivalents	$ (22,914)	$ 51,221

Net Cash Used in Operating Activities. Net cash used in operating activities for both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was approximately $71.4 million during the nine months ended September 30, 2016, compared to approximately $31.4 million during the same period of 2015. The increase in cash used in operating activities was driven primarily by an increase in activities relating to development of entrectinib, taladegib and our other product candidates and higher salaries, benefits and personnel-related costs resulting from higher headcount to support our expanded clinical and non-clinical development activities.

Net Cash Used in Investing Activities. Net cash used in investing activities was approximately $5.3 million during the nine months ended September 30, 2016, compared to approximately $39.2 million used in such activities during the same period of 2015. The cash used in investing activities in both periods was primarily due to net purchases of investment securities, partially offset by the funds used to acquire property and equipment of $1.8 million during the

first half of 2016 and $2.6 million during the same period of 2015.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was approximately $53.8 million during the nine months ended September 30, 2016, compared to the approximately $121.8 million provided by financing activities during the same period of 2015. Cash provided by financing activities during the nine months ended September 30, 2016 and 2015 was primarily the result of the funds raised through sales of common stock.

Funding Requirements

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

As of September 30, 2016, we had approximately $152.5 million in cash, cash equivalents and investment securities. We expect that our existing cash, cash equivalents and investment securities will enable us to fund our operations and capital expenditure requirements for at least the next twelve months. We expect to need to obtain additional funding in future periods, however, in order to continue our operations and pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our development programs;

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

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

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

limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern.

Off-Balance Sheet Arrangements

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

Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue anticipate, intend, seek, plan, expect, should or would, or the negative of these terms or other comparable Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the results of our research and development activities, including uncertainties relating to the preclinical and clinical testing of our product candidates; the early stage of our product candidates presently under development; our need for additional funds in order to pursue our business plan and the uncertainty of whether we will be able to obtain the funding we need; our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates, and any future product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate; our ability to retain or hire key scientific or management personnel; our ability, potentially with partners, to validate, develop and obtain regulatory approval of

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companion diagnostics for our product candidates; our ability to protect our intellectual property rights, including patent and other intellectual property rights; our dependence on third-party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators; our ability to develop and/or obtain successful sales and marketing capabilities in the future as needed; the size and growth of the potential markets for any of our product candidates, and the rate and degree of market acceptance of any of our product candidates; competition in our industry; the impact of healthcare reform legislation; regulatory developments in the United States and foreign countries; and other risks detailed under Part I Item 1A Risk Factors in our most recent Annual Report on Form 10-K, as updated by our subsequent filings under the Exchange Act.

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Fluctuation Risk

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. Because of the short-term maturities of our cash equivalents and marketable investment securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our marketable investment securities. If a 1.0% change in interest rates were to have occurred on September 30, 2016, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We have a loan arrangement with SVB and Oxford under which we have borrowed $32.0 million, which accrues interest at a variable rate of interest equal to the Prime Rate plus 4.35% (7.85% at September 30, 2016). If a 1.0% change in interest rates were to have occurred on September 30, 2016, this change would not have had a material impact on our interest costs over the life of the loan arrangement.

Foreign Currency Exchange Risk

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

Inflation Risk

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

Item 4. Controls and Procedures

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

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2016 at the reasonable assurance level.

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

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2015 includes a detailed discussion of our risk factors under the heading Part I Item 1A Risk Factors. There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, other than as previously disclosed in our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2016, and March 31, 2016, or as set forth below. In evaluating our business, you should carefully consider the risk factors discussed in our Annual Report on Form 10-K, as updated by our subsequent filings under the Exchange Act. The occurrence of any of the risks discussed in such filings, or other events that we do not currently anticipate or that we currently deem immaterial, could harm our business, prospects, financial condition and results of operations. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Except with respect to our trademarks, the trademarks, trade names and service marks appearing in this report are the property of their respective third party owners.

Risks Related to Our Financial Position and Capital Requirements

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

We are a development-stage biopharmaceutical company with a limited operating history. We have not generated any material revenue to date and are not profitable, and have incurred losses in each year since our inception. Our net loss for the year ended December 31, 2015 was $92.5 million, and our net loss for the nine months ended September 30, 2016 was $75.4 million. As of September 30, 2016, we had an accumulated deficit of $223.5 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are currently focused on the development of our clinical and preclinical development programs, which we believe will result in our continued incurrence of significant research and development and other expenses related to those programs. If the non-clinical or clinical trials for any of our product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital.

Risks Related to the Development of Our Product Candidates

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

To date, we have invested significant efforts in the acquisition of our drug programs from Nerviano Medical Sciences S.r.l., or NMS, Teva and Lilly. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize products resulting from these programs and any others we may develop or acquire in the future, which may never occur.

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

- conduct substantial clinical development;
- manage clinical, preclinical and manufacturing activities;
- complete development of a proposed commercial formulation;
- achieve regulatory approvals;
- establish manufacturing relationships;
- build a commercial sales and marketing team, if we choose to market any such product ourselves, or enter into a collaboration to access sales and marketing functions;
- develop and implement marketing and reimbursement 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.

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If the results of our ongoing or planned clinical trials of entrectinib and any other product candidates are not successful, we may not be able to use those results as the basis for advancing these product candidates into further clinical development. In that case, we may not have the resources to conduct new clinical trials, and/or we may determine that further clinical development of these product candidates is not justified and may decide to discontinue the programs. If the results of preclinical testing for our other product candidates are not successful, we may not be able to use those results as the basis for advancing those programs into further development. If studies of our product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects could be substantially harmed, particularly if the product candidates for which development has ceased are at the clinical development stage.

Risks Related to Our Dependence on Third Parties

We plan to rely solely 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 or if we are otherwise unable to secure sufficient quantities.

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 solely on third-party manufacturers for those services. We currently have a limited supply of entrectinib and our other product candidates. We have a limited number of supply arrangements for entrectinib and our other preclinical and clinical product candidates. In addition, we have only a limited clinical supply of taladegib, and we must seek to establish clinical supply agreements with third parties for future supplies. We do not currently have arrangements in place for commercial supply of bulk drug substance or drug products. We may not be able to establish these or any other supply relationship when needed, on reasonable terms, or at all, in particular given the limited number of qualified third-party manufacturers and existing limitations on their production capacity. 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 do not control the manufacturing process of, and are and will continue to 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. In recent years, the FDA has issued complete response letters and declined to approve marketing applications submitted by various companies due to adverse findings at the contract manufacturers facilities that were identified in connection with pre-approval inspections at these facilities. Any such failure by any of our contract manufacturers would significantly impact our ability to continue 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 or for commercial sale. We do not have, nor do we expect to enter, any agreements for the production of these raw materials, and we do not expect to have any control over the process or timing of our manufacturers acquisition of raw materials needed to produce our product

candidates. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing preclinical study or clinical trial due to a manufacturer s need to replace a third-party supplier of raw materials could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. Additionally, if our manufacturers or we are unable to purchase these raw materials to commercially produce any of our product candidates that gain regulatory approval, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

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

We have in-licensed from Lilly the use, development and commercialization rights for our taladegib programs, and we have assumed license agreements from Teva that include rights and obligations relating to our RXDX-105 and RXDX-106 programs. As a result, our current business plans are dependent upon our satisfaction of certain conditions to the maintenance of those license agreements and the rights we license under them. Each of the license agreements provides that we are subject to diligence obligations relating to the commercialization and development of product candidates, milestone payments, royalty payments and other obligations. In addition to

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these license agreements, we may seek to enter into additional agreements with other third parties in the future granting similar license rights with respect to other potential product candidates. If we fail to comply with any of the conditions or obligations or otherwise breach the terms of any of these license agreements, or any future license agreement we may enter on which our business or product candidates are dependent, the licensor may have the right to assert a claim for damages against us or 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. If we become liable for material damages under any of these license agreement, this could would materially harm our business, prospects, financial condition and results of operations. Similarly, the loss of the rights licensed to us under these license agreements, or any future license agreement that we may enter granting us rights on which our business or product candidates are dependent, would eliminate our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of October 31, 2016, a total of 41.7 million shares of our common stock were outstanding. Of those shares, approximately 37.3 million were freely tradable, without restriction, in the public market. Such shares represented approximately 90% of our outstanding shares of common stock as of that date. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, our effective Registration Statements on Form S-8 and any future registration of such shares under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As of October 31, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 50% of our outstanding voting stock (which includes shares they had the right to acquire within 60 days). Accordingly, our directors and executive officers and large stockholders have significant influence over our affairs due to their substantial ownership coupled with the positions of some of these stockholders on our management team, and have substantial voting power to approve matters requiring the approval of our stockholders. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership in our Board of Directors and management team and certain other large stockholders may prevent or discourage unsolicited acquisition proposals or offers for our common stock that some of our stockholders may believe are in their best interest.

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

Not applicable.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1	Agreement and Plan of Reorganization, dated May 7, 2013, by and between Ignyta, Inc. and Actagene Oncology, Inc. (incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
2.2	Agreement and Plan of Merger and Reorganization, dated October 31, 2013, by and among Ignyta, Inc. (then known as Infinity Oil & Gas Company), IGAS Acquisition Corp., and Ignyta, Inc. (then known as Ignyta Operating, Inc.) (incorporated by reference to Exhibit 2.2 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
2.3	Agreement and Plan of Merger, dated June 12, 2014, by and among Ignyta, Inc. (then known as Ignyta Operating, Inc.), and its parent entity Ignyta, Inc. (incorporated by reference to Exhibit 2.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
3.1	Second Amended and Restated Certificate of Incorporation of Ignyta, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
3.2	Amended and Restated Bylaws of Ignyta, Inc. (incorporated by reference to Exhibit 3.2 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
4.1	Form of Common Stock certificate (incorporated by reference to Exhibit 4.1 to the Company s Report on Form 8-K12B filed with the SEC on June 13, 2014).
4.2	Warrant to Purchase Stock, issued to Silicon Valley Bank on June 25, 2012 (incorporated by reference to Exhibit 10.5 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
4.3	Warrant to Purchase Stock, issued to Silicon Valley Bank on February 27, 2013 (incorporated by reference to Exhibit 10.6 to the Company s Current Report on Form 8-K filed with the SEC on November 1, 2013).
4.4	Warrant to Purchase Common Stock, dated November 6, 2013, issued to Nerviano Medical Sciences S.r.l. (incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed with the SEC on November 7, 2013).
4.5	Warrant to Purchase Stock, issued to Silicon Valley Bank on September 30, 2014 (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed with the SEC on October 1, 2014).
4.6	Warrant to Purchase Stock, issued to Life Science Loans, LLC on September 30, 2014 (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed with the SEC on October 1, 2014).
4.7	Warrant to Purchase Stock, issued to Silicon Valley Bank on September 30, 2015 (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed with the SEC on September 30, 2015).
4.8	

	Warrant to Purchase Stock, issued to Life Science Loans, LLC on September 30, 2015 (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed with the SEC on September 30, 2015).
4.9	Warrant to Purchase Common Stock, issued to Silicon Valley Bank on June 30, 2016 (incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed with the SEC on July 1, 2016).
4.10	Warrant to Purchase Stock, issued to Oxford Finance LLC on June 30, 2016 (incorporated by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed with the SEC on July 1, 2016).
4.11	Warrant to Purchase Stock, issued to Oxford Finance LLC on June 30, 2016 (incorporated by reference to Exhibit 4.3 to the Company s Current Report on Form 8-K filed with the SEC on July 1, 2016).
4.12	Warrant to Purchase Stock, issued to Oxford Finance LLC on June 30, 2016 (incorporated by reference to Exhibit 4.4 to the Company s Current Report on Form 8-K filed with the SEC on July 1, 2016).
4.13	Warrant to Purchase Stock, issued to Oxford Finance LLC on June 30, 2016 (incorporated by reference to Exhibit 4.5 to the Company s Current Report on Form 8-K filed with the SEC on July 1, 2016).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

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Exhibit Number	Description of Exhibit
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

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SIGNATURES

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

IGNYTA, INC.

Date: November 7, 2016

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

President and Chief Executive Officer

Date: November 7, 2016

By: /s/ Jacob M. Chacko, M.D.
Jacob M. Chacko, M.D.

Chief Financial Officer