Ignyta, Inc.
Form 10-Q
August 10, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36344

Ignyta, Inc.

(Exact name of registrant as specified in its charter)

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

(858) 255-5959

(Registrant s telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

The number of outstanding shares of the registrant s common stock, par value $0.0001 per share, as of July 31, 2015, was 29,598,915.

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IGNYTA, INC.

FORM 10-Q QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

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PART I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Ignyta, Inc.

Condensed Balance Sheets

	June 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 53,555,536	$ 6,345,663
Short-term investment securities	55,097,748	63,200,563
Prepaid expenses and other current assets	2,565,488	1,731,521
Total current assets	111,218,772	71,277,747
Long-term investment securities	57,734,526	7,086,700
Fixed assets, net	7,567,761	6,280,909
Other assets	523,445	658,716
Total assets	$ 177,044,504	$ 85,304,072
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,772,335	$ 975,264
Accrued expenses and other liabilities	6,863,174	4,929,601
Note payable, current portion	1,166,667	1,400,000
Lease payable, current portion	176,084	171,638
Total current liabilities	9,978,260	7,476,503
Note payable, net of current portion and discount	19,196,233	18,830,136
Lease payable, net of current portion	255,020	344,188
Other long-term liabilities	2,454,274	2,705,319
Total liabilities	31,883,787	29,356,146
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par; 10,000,000 shares authorized; no shares issued or outstanding		
Common stock, $0.0001 par; 150,000,000 shares authorized; 29,598,915 and 19,584,769 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	2,960	1,958
Additional paid-in capital	237,421,462	111,561,894

Accumulated deficit	(92,188,914)	(55,562,586)
Accumulated other comprehensive loss	(74,791)	(53,340)
Total stockholders equity	145,160,717	55,947,926
Total liabilities and stockholders equity	$ 177,044,504	$ 85,304,072

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

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Ignyta, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Revenue	$	$ 150,000	$	$ 150,000
Operating expenses:				
Research and development	8,796,443	3,575,787	29,011,889	5,758,367
General and administrative	3,854,634	2,038,721	6,621,091	3,800,269
Total operating expenses	12,651,077	5,614,508	35,632,980	9,558,636
Loss from operations	(12,651,077)	(5,464,508)	(35,632,980)	(9,408,636)
Other income (expense):				
Interest expense	(603,146)	(25,637)	(1,204,920)	(52,658)
Other income (expense)	134,500	67,622	211,573	(68,020)
Total other income (expense)	(468,646)	41,985	(993,347)	(120,678)
Net loss	$ (13,119,723)	$ (5,422,523)	$ (36,626,327)	$ (9,529,314)
Basic and diluted net loss per share	$ (0.51)	$ (0.28)	$ (1.58)	$ (0.56)
Weighted average shares basic and diluted	25,927,708	19,578,733	23,211,749	17,054,031
Comprehensive loss:				
Net loss	$ (13,119,723)	$ (5,422,523)	$ (36,626,327)	$ (9,529,314)
Unrealized gain (loss) on available-for-sale securities	(49,698)	36,678	(21,451)	5,562
Comprehensive loss	$ (13,169,421)	$ (5,385,845)	$ (36,647,778)	$ (9,523,752)

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

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Ignyta, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Six months ended June 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (36,626,327)	$ (9,529,314)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development charge associated with asset acquisition	11,880,000	
Stock-based compensation	2,103,784	817,330
Depreciation and amortization of fixed assets	793,205	111,708
Accretion and amortization on debt securities	502,223	285,540
Amortization of non-cash financing costs	132,764	147,463
Other		53,837
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other assets	53,373	(226,912)
Accounts payable	797,071	1,176,166
Accrued expenses and other liabilities	1,682,527	912,681
Net cash used in operating activities	(18,681,380)	(6,251,501)
Cash flows from investing activities:		
Purchases of investment securities	(85,354,050)	(62,332,770)
Maturities and sales of investment securities	41,533,296	1,471,219
Purchases of fixed assets	(2,080,057)	(1,711,668)
Net cash used in investing activities	(45,900,811)	(62,573,219)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	111,588,519	51,581,843
Proceeds from exercise of stock options	288,267	5,472
Payments on leases payable	(84,722)	
Repurchase of common stock		(1,440)
Net cash provided by financing activities	111,792,064	51,585,875
Net change in cash and cash equivalents	47,209,873	(17,238,845)
Cash and cash equivalents at beginning of period	6,345,663	51,803,716
Cash and cash equivalents at end of period	$ 53,555,536	$ 34,564,871
Supplemental disclosures of cash flow information:		
Interest paid	$ 921,065	$ 292,178

Income taxes paid	$		$	5,304
Noncash investing and financing activities:				
Leasehold improvements paid for by landlord	$		$	100,000
Unrealized gain (loss) on available-for-sale securities	$	(21,451)	$	5,562

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

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Ignyta, Inc.

Notes to Condensed Financial Statements

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization and Nature of Operations

Ignyta, Inc. (Ignyta or the Company) is incorporated in the state of Delaware and was founded in 2011 (with the name NexDx, Inc.). The Company changed its name to Ignyta, Inc. on October 8, 2012. The Company is a precision oncology biotechnology company dedicated to discovering or acquiring, then developing and commercializing, targeted new drugs for cancer patients whose tumors harbor specific molecular alterations, as well as novel chemotherapeutics that can potentially provide additional benefit to cancer patients. The Company is pursuing an integrated therapeutic and diagnostic, or Rx/Dx, strategy, where it anticipates pairing its product candidates with biomarker-based companion diagnostics that are designed to identify the patients who are most likely to benefit from the precisely targeted drugs the Company develops.

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

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

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information, the instructions to Form 10-Q and related SEC rules and regulations. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management s opinion, the accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results for the interim periods presented. Interim financial results are not necessarily indicative of results anticipated for the full year. These unaudited financial statements should be read in conjunction with the Company s audited financial statements and footnotes included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Liquidity

The Company had negative cash flow from operations of approximately $18.7 million during the first half of 2015 and, as of June 30, 2015, had an accumulated deficit of approximately $92.2 million. The Company is focused primarily on its development programs, and management believes such activities will result in the continued incurrence of significant research and development and other expenses related to those programs. The Company expects that it will need additional capital to further fund development of, and seek regulatory approvals for, its product candidates, and begin to commercialize any approved products. If the clinical trials for any of the Company s products fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of its product candidates, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if it achieves profitability in the future, the Company may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash on hand and through additional financing from existing and prospective investors. The Company cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or to its stockholders.

As of June 30, 2015, the Company had cash, cash equivalents and investment securities totaling $166.4 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. 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.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Cash and Cash Equivalents

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

Investment Securities

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

Fair Value of Financial Instruments

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

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

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

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are

observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

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

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

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

Credit Risk

Cash is invested in accordance with a policy approved by the Company s board of directors which specifies the categories, allocations, and ratings of securities that the Company may consider for investment. Management does not believe that the Company s cash, cash equivalents and available-for-sale investment securities have significant risk of default or illiquidity. This determination is based on discussions with the Company s treasury managers and a review of the Company s holdings. While the Company believes that its cash, cash equivalents and available-for-sale investment securities are well diversified and do not contain excessive risk, the Company cannot provide absolute assurance that its investments will not be subject to future adverse changes in market value.

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

Clinical Trial and Pre-Clinical Study Accruals

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

Research and Development

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

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

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

Stock-Based Compensation

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

Net Loss per Share

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

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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 4.1 million and 2.4 million shares as of June 30, 2015 and 2014, respectively.

Recent Accounting Pronouncements

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

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

Reclassifications.

Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

3. ASSET ACQUISITION

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

RXDX-105, a small molecule inhibitor of RET, BRAF and EGFR that is currently in a Phase I/II dose escalation clinical trial;

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

RXDX-107, a new chemical entity comprising an alkyl ester of bendamustine encapsulated in human serum albumin (HSA) to form nanoparticles; and

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

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

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

Under the provisions of the asset purchase agreement, the Company paid approximately $0.9 million to Cephalon for drug development supplies, which was included in research and development expenses for the first quarter of 2015. Concurrent with the above transaction, Cephalon also entered into a subscription agreement with the Company whereby Cephalon agreed to purchase an additional 1,500,000 shares of the Company s common stock at a price of $10.00 per share (see Note 9).

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In connection with the asset purchase agreement, the Company entered into a registration rights agreement with Cephalon pursuant to which the Company has agreed to register the shares of the Company s common stock held by Cephalon. Under the terms of the registration rights agreement, the Company is required to use best efforts to file a registration statement with the SEC on or before December 17, 2015 and to cause such registration statement to be declared effective by the SEC within 90 days after the date the registration statement is filed. The Company may be liable for liquidated damages if it fails to meet such timelines or if the registration statement ceases to remain effective after being declared effective, subject to certain exceptions. The amount of the liquidated damages per applicable thirty-day period is one percent of the aggregate purchase price of the registrable securities then held by each holder, subject to an aggregate cap of ten percent. The Company also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement and payment of certain expenses.

4. INVESTMENT SECURITIES

Investments

The following tables summarize the Company s investment securities as of June 30, 2015 and December 31, 2014 (in thousands):

	June 30, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale securities:				
Commercial paper, short-term	$ 2,500	$	$	$ 2,500
Corporate debt securities, short-term	52,626	7	(35)	52,598
U.S. government and agency obligations, long-term	19,015	17	(1)	19,031
Corporate debt securities, long-term	38,766	7	(70)	38,703
Total	$ 112,907	$ 31	$ (106)	$ 112,832

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

All of the Company s available-for-sale investment securities held at June 30, 2015 had maturity dates of less than 18 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 was in a material unrealized loss position at June 30, 2015. The Company reviewed its investment holdings as of June 30, 2015 and determined that its unrealized losses were not considered to be other-than-temporary based upon (i) the financial strength of the issuing institution and (ii) the fact that all securities have been in an unrealized loss position for less than twelve months. As such, the Company has not recognized any impairment in its financial statements related to its available-for-sale securities.

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

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5. FAIR VALUE MEASUREMENTS

The Company holds available-for-sale securities that consist of highly liquid, investment grade debt securities. The Company determines the fair value of its available-for-sale securities based upon one or more valuations reported by its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets or liabilities (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures. The fair value of the Company s cash, cash equivalents and available-for-sale investment securities at June 30, 2015 and December 31, 2014 were as follows (in thousands):

	June 30, 2015				December 31, 2014			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 53,556	$	$	$ 53,556	$ 6,346	$	$	$ 6,346
Short-term investments:								
Commercial paper		2,500		2,500		3,896		3,896
Corporate debt securities		52,598		52,598		59,305		59,305
Total short-term investments		55,098		55,098		63,201		63,201
Long-term investments:								
U.S. government and agency obligations	19,031			19,031				
Corporate debt securities		38,703		38,703		7,087		7,087
Total long-term investments	19,031	38,703		57,734		7,087		7,087
Total assets measured at fair value	$ 72,587	$ 93,801	$	$ 166,388	$ 6,346	$ 70,288	$	$ 76,634

6. FIXED ASSETS

Carrying Value of Fixed Assets

Fixed assets consisted of the following at June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
Manufacturing and lab equipment	$ 5,723,480	$ 3,837,967
Leasehold improvements	2,348,897	2,326,963
Computer equipment and software	574,131	471,415
Office furniture	348,789	278,895

Fixed assets, gross	8,995,297	6,915,240
Less accumulated depreciation and amortization	(1,427,536)	(634,331)
Fixed assets, net	$ 7,567,761	$ 6,280,909

Depreciation expense was $421,126 and $793,205 for the three and six months ended June 30, 2015, respectively, and $63,108 and $111,708 for the three and six months ended June 30, 2014, respectively.

Capital Leases

The net book value of the Company s equipment under capital leases was $555,442 as of June 30, 2015, which reflected accumulated life-to-date depreciation of $80,289. Depreciation expense on this equipment totaled $31,787 and $80,289 for the three and six months ended June 30, 2015, respectively. These assets were acquired late in the fourth quarter of 2014, and as such, there was no depreciation expense reflected in the Company s 2014 operating results related to these assets. Remaining minimum payments under capital leases totaled $431,104 as of June 30, 2015.

7. NOTES PAYABLE

On September 30, 2014, the Company entered into an amended and restated loan and security agreement with Silicon Valley Bank (SVB), which was subsequently amended on June 5, 2015 (the New Loan Agreement). The New Loan Agreement replaced the prior loan and security agreement (the Loan Agreement) which was first entered into in June 2012, amended in February 2013 and amended and restated in December 2013. The amount borrowed under the New Loan Agreement was increased from $10,000,000 to $21,000,000, with an option to receive an additional $10,000,000, which may be drawn down at any time prior to September 30, 2015 provided the Company has initiated any Phase II clinical study of entrectinib (formerly called RXDX-101) and subject to other customary conditions for funding. All principal and interest due on the prior Loan Agreement was paid in full and the Company was advanced the net proceeds of the New Loan Agreement in September 2014. In connection with entering into the New Loan Agreement, the Company issued to SVB and its affiliate warrants to purchase an aggregate of 37,849 shares of its common stock with a term of seven years. The fair value of the warrants has been recorded as a debt discount and is being amortized to interest expense over the term of the New Loan Agreement.

Payments of principal and interest on the New Loan Agreement are due on a fully amortized basis of 36 months in equal monthly installments, commencing after an eighteen-month period of interest only payments, such that all amounts owed under the New Loan

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Agreement will mature on April 1, 2019. In accordance with the provisions of the New Loan Agreement, the number of months of interest-only payments and the number of months over which the principal will be amortized were each increased by six months upon consummation of the Company s stock offering in June 2015 (see Note 9). Upon the final maturity date, the Company will also owe to the lender a final payment equal to 3% of the full principal amount under the New Loan Agreement. The final payment of $630,000, which is based on the initial amount borrowed under the New Loan Agreement, is presented as a debt discount on the related debt to be amortized to interest expense. Interest on the note was fixed on the date of funding at 8.6%.

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

Future minimum principal payments under the Company s notes payable are as follows:

Year ending December 31,	
2015 (6 months)	$
2016	4,666,667
2017	7,000,000
2018	7,000,000
2019	2,333,333
Total	$ 21,000,000

If the Company draws down the second loan tranche under the New Loan Agreement, it will issue to SVB and its affiliate 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 $135,500 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 loan tranche and (b) the closing price of the Company s common stock on the Nasdaq Capital Market on the funding date of the second loan tranche, at an exercise price equal to such divisor.

8. COMMITMENTS AND CONTINGENCIES

License agreements

Entrectinib. The Company entered into a license agreement with Nerviano Medical Sciences S.r.l. (NMS) on October 10, 2013, which was amended on October 25, 2013, became effective on November 6, 2013, and was amended December 12, 2014. The agreement grants the Company exclusive global rights to develop and commercialize entrectinib, as well as a second product candidate, RXDX-102. As a result of the Phase I results relating to entrectinib that have been seen to date, the Company designated RXDX-102 as a back-up compound to entrectinib. Accordingly, the Company will not devote further development resources to RXDX-102. The Company s development rights under the license agreement are exclusive for the term of the agreement with respect to entrectinib and RXDX-102 and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with

activity against the target proteins of entrectinib and RXDX-102, and include the right to grant sublicenses. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on either or both of entrectinib and RXDX-102, at its expense.

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

RXDX-103 and RXDX-104. On August 4, 2014, the Company entered into a second license agreement with NMS. The agreement grants the Company exclusive global rights to develop and commercialize RXDX-103, as well as a second development program, RXDX-104. Based on preclinical activities relating to RXDX-104, in December 2014, the Company decided to discontinue development of RXDX-104, and the Company will not devote further development resources to this program. The Company s rights

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under the agreement are exclusive for the term of the agreement with respect to RXDX-103 and RXDX-104 and also, as to NMS, are exclusive for a five-year period with respect to any product candidate with activity against the target proteins of RXDX-103 and RXDX-104, subject to NMS s right to develop and commercialize a predecessor compound to RXDX-103 solely for animal indications. The Company is obligated under the license agreement to use commercially reasonable efforts to develop and commercialize a product based on either or both of RXDX-103 and RXDX-104, at its expense.

Under the license agreement, the Company made an up-front payment to NMS of $3.5 million in August 2014, which was expensed to research and development (as no future benefit was determined to exist at that time). When and if commercial sales of a product based on either of RXDX-103 or RXDX-104 begin, the Company will be obligated to pay NMS tiered royalties ranging from a mid-single digit percentage to a low double digit percentage of net sales, depending on annual amounts of net sales, with standard provisions for royalty offsets to the extent it is required to obtain any rights from third parties to commercialize either RXDX-103 or RXDX-104. The Company is also required to make development and regulatory milestone payments to NMS of up to $68.0 million in the aggregate for RXDX-103 if specified clinical study initiations and regulatory approvals are achieved across multiple products or indications.

RXDX-105 and RXDX-106. In connection with the March 2015 asset acquisition from Cephalon, the Company assumed all rights and obligations under the collaboration agreement dated November 3, 2006, as amended April 17, 2009, between Cephalon, Inc. and Daiichi Sankyo Company, Limited (Daiichi Sankyo), as successor-in-interest to Ambit Biosciences Corporation. The collaboration was for the purpose of identifying and developing clinical candidates that demonstrate activity towards the two designated target kinases of the collaboration: the BRAF kinase and the AXL kinase. Under the agreement, both parties contributed certain intellectual property to the collaboration and agreed to a period of exclusivity during which neither party would engage in any research related to a collaboration target compound with any third-party. The collaboration portion of the agreement ended in November 2009, but the agreement remains in effect on a product-by-product, country-by-country basis until all royalty obligations expire. Both parties have a right to terminate the agreement if the other party enters bankruptcy or upon an uncured breach by the other party. The Company may also terminate the agreement in its discretion upon 90 days written notice to Daiichi Sankyo. The Company is solely responsible for worldwide clinical development and commercialization of collaboration compounds, subject to the option of Daiichi Sankyo, exercisable during certain periods following completion of the first proof-of-concept study in humans and only with the consent of the Company, to co-develop and co-promote RXDX-105. If the Company decides to discontinue development of the RXDX-105 program, it must give written notice to Daiichi Sankyo, which will have the right to assume control of that program, subject to diligence obligations and payment of the milestones and royalties to the Company that would otherwise have been paid to Daiichi Sankyo had the Company maintained responsibility for the program.

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

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

The license agreement requires the Company to make development, regulatory and sales milestone payments to CRT of up to $57.0 million in the aggregate. When and if commercial sales of a product based on the licensed intellectual property begin, the Company will be obligated to pay CRT tiered royalties ranging from a mid-single digit percentage to a low double digit percentage of net sales, depending on annual amounts of net sales. Royalties are payable to CRT on a product-by-product, country-by-country basis beginning on the date of the first commercial sale in a country and ending on the later of 10 years after the date of such sale in that country or the expiration date of the last to expire licensed patent covering the product in that country.

Commitments

The Company has entered into agreements with contract research organizations for clinical studies to be conducted both within and outside the U.S. for its product candidates. The aggregate cost under these arrangements is expected to be approximately $24.0 million over a two-year period, of which approximately $9.1 million has been incurred to date.

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The Company leases office space and lab equipment under non-cancelable operating leases expiring on various dates through October 2019. Future minimum lease payments under the Company s operating leases totaled $3.6 million as of June 30, 2015.

9. STOCKHOLDERS EQUITY

Authorized Shares

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

Restricted Stock

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

Approximately 28,516 shares associated with restricted stock arrangements were subject to future vesting as of June 30, 2015.

Stock Offerings

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

In March 2015, concurrent with its asset acquisition agreement with Cephalon (see Note 3), the Company issued and sold 4,158,750 shares of common stock at $10.00 per share to Cephalon and several additional investors in a secondary public offering. The net proceeds from this offering totaled approximately $41.4 million (after deducting transaction costs of $149,000).

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

Warrants

Warrants to purchase up to an aggregate of 43,925 shares of the Company s common stock were outstanding as of June 30, 2015. These warrants have exercise prices ranging from $3.00 to $7.52 per share, and expire at various dates through September 30, 2021.

10. EQUITY AWARDS

Equity Incentive Plans

The Company adopted the 2014 Incentive Award Plan (the 2014 Plan) on June 11, 2014. The 2014 Plan provides for the issuance of equity awards to employees and non-employees of up to 3,000,000 shares, plus one share for each share subject to a stock option that was outstanding under the Company s 2011 Stock Incentive Plan, as amended (the 2011 Plan) prior to the effective date of the 2014 Plan that expires, is forfeited or is settled in cash. As of June 30, 2015, 1,181,297 shares remain available under the 2014 Plan. Prior to the adoption of the 2014 Plan, the Company granted equity awards under the 2011 Plan and the 2014 Employment Inducement Incentive Award Plan (the 2014 Inducement Plan). No additional equity grants may be made by the Company under either the 2011 Plan or the 2014 Inducement Plan.

In July 2015, the Company adopted the 2015 Employment Inducement Incentive Award Plan (the 2015 Inducement Plan). The 2015 Inducement Plan provides for the issuance of equity awards to employees and non-employees of up to 2,000,000 shares. Awards under the 2015 Inducement Plan may only be made to an employee who has not previously been an employee or member of the board of directors of the Company or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

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Stock Option Activity

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

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Term	Aggregate Intrinsic Value
Balance at December 31, 2014	2,991,656	$ 6.67	9.21	$ 2,482,181
Granted	1,331,491	8.69		
Exercised	(47,363)	6.17		
Forfeited	(279,468)	7.57		
Balance at June 30, 2015	3,996,316	$ 7.28	9.02	$ 29,569,040
Exercisable at June 30, 2015	809,983	$ 5.58	8.42	$ 7,706,321

Options granted under the Company s equity plans are exercisable at various dates and will expire no more than ten years from their dates of grant. The exercise price of each option to be granted under the 2014 Plan shall be determined by the administrator of the 2014 Plan, which is the Company s board of directors or the compensation committee thereof, and shall not be less than 100% of the fair market value of the Company s common stock on the date the option is granted. The exercise price of each option to be granted under the 2015 Inducement Plan shall be determined by the administrator of the 2015 Inducement Plan, which is the compensation committee of the Company s board of directors, and shall not be less than 100% of the fair market value of the Company s common stock on the date the option is granted. For holders of more than 10% of the Company s total combined voting power of all classes of stock, incentive stock options may not be granted at less than 110% of the fair market value of the Company s common stock on the date of grant and for a term not to exceed five years.

Restricted Stock Units

In 2015, the Company issued 90,000 restricted stock units (RSUs) to employees under the 2014 Plan with vesting to occur on either the fourth or fifth anniversary of the grant date. All of these RSUs were outstanding and subject to future vesting as of June 30, 2015.

Fair Value of Equity Awards

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

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

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

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

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

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

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

	Fiscal 2015
Volatility	68.5%
Risk free interest rate	1.60%
Dividend yield	0.00%
Expected life of option	6.1 years

The estimated weighted-average fair value of stock options granted during fiscal 2015 was $5.35 per share.

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Stock-Based Compensation

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Included in research and development	$ 447,598	$ 134,802	$ 916,212	$ 309,443
Included in general and administrative	623,969	246,249	1,187,572	507,887
Total	$ 1,071,567	$ 381,051	$ 2,103,784	$ 817,330

Unrecognized stock-based compensation expense related to unvested awards granted under the Company s equity incentive plans totaled $13.0 million as of June 30, 2015, and is expected to be recognized over a weighted-average period of 3.2 years.

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

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

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

Overview

We are a precision oncology biotechnology company dedicated to discovering or acquiring, then developing and commercializing, targeted new drugs for cancer patients whose tumors harbor specific molecular alterations, as well as novel chemotherapeutics that can potentially provide additional benefit to cancer patients. We are pursuing an integrated therapeutic and diagnostic, or Rx/Dx, strategy, where we anticipate pairing our product candidates with biomarker-based companion diagnostics that are designed to identify the patients who are most likely to benefit from the precisely targeted drugs we develop.

Our current development plans focus on our pipeline:

- entrectinib, formerly called RXDX-101, a small molecule tyrosine kinase inhibitor directed to the Trk family tyrosine kinase receptors (TrkA, TrkB and TrkC), ROS1 and ALK proteins, which is in two Phase I/II clinical studies in molecularly defined patient populations for the treatment of solid tumors;

RXDX-105, a small molecule inhibitor of RET, BRAF and EGFR that is currently in a Phase I/II clinical trial for the treatment of solid tumors;

RXDX-107, a new chemical entity comprising an alkyl ester of bendamustine encapsulated in human serum albumin (HSA) to form nanoparticles for which the U.S. Food and Drug Administration, or FDA, has cleared our Investigational New Drug application, or IND;

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

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

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

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

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

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

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

We do not track our employee and facility related research and development costs by project, as we typically use our employee and infrastructure resources across multiple research and development programs. We believe that the allocation of such costs would be arbitrary and would not be meaningful. We have not historically tracked external development costs by program as the majority of our development spend was focused on the development and clinical trials of entrectinib. We have contracted with clinical research organizations to manage our clinical trials under agreed

upon budgets, with oversight by our clinical program managers. Any deviations from the budgets must be approved by us in writing, prior to commencement of the work. Our internal research and development costs are controlled through our internal budget and forecast process and subject to quarterly review and analysis of budget versus actual expenditures.

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

- establishing an appropriate safety profile with toxicology studies adequate to submit to the FDA in an IND or comparable applications to foreign regulatory authorities;

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

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

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

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

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

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

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

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

General and Administrative Expenses

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

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

Critical Accounting Policies and Estimates

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

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

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

Research and Development

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

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

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

Clinical Trial and Pre-Clinical Study Accruals

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