Ignyta, Inc.
Form 10-Q
August 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-36344

Ignyta, Inc.

(Exact name of registrant as specified in its charter)

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

(858) 255-5959

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of July 31, 2017, the registrant had 56,253,915 shares of common stock ($0.0001 per share par value) outstanding.

IGNYTA, INC.

FORM 10-Q — QUARTERLY REPORT

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

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PART I — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements
Ignyta, Inc.

Condensed Balance Sheets

(In thousands, except share data)

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 61,147	$ 24,340
Short-term investment securities	104,231	83,637
Other current assets	3,958	3,873
Total current assets	169,336	111,850
Long-term investment securities	4,000	24,983
Property and equipment, net	4,675	6,270
Other long-term assets	1,520	1,811
Total assets	$ 179,531	$ 144,914
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 17,420	$ 13,510
Obligation due to licensor	3,709	—
Accrued compensation and benefits	2,057	4,007
Total current liabilities	23,186	17,517
Term loan, net of discount	29,838	29,517
Other long-term liabilities	11,628	3,110
Total liabilities	64,652	50,144
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; 56,237,915 and 41,665,779 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	6	4
Additional paid-in capital	435,061	346,549
Accumulated other comprehensive loss	(91)	(123)
Accumulated deficit	(320,097)	(251,660)
Total stockholders' equity	114,879	94,770
Total liabilities and stockholders' equity	$ 179,531	$ 144,914

See the accompanying notes to these unaudited condensed financial statements.

Ignyta, Inc.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$22,172	$20,019	$56,218	$39,800
General and administrative	5,496	5,499	11,065	10,726
Total operating expenses	27,668	25,518	67,283	50,526
Loss from operations	(27,668)	(25,518)	(67,283)	(50,526)
Other income (expense):				
Interest expense	(829)	(800)	(1,641)	(1,591)
Other income (expense)	219	364	486	671
Loss on debt extinguishment	—	(696)	—	(696)
Total other income/ (expense), net	(610)	(1,132)	(1,155)	(1,616)
Net loss	$(28,278)	$(26,650)	$(68,438)	$(52,142)
Comprehensive loss:				
Net loss	$(28,278)	$(26,650)	$(68,438)	$(52,142)
Net unrealized gain (loss) on investment securities	7	47	31	312
Comprehensive loss	$(28,271)	$(26,603)	$(68,407)	$(51,830)
Net loss per share:				
Net loss per share – basic and diluted	$(0.56)	$(0.70)	$(1.49)	$(1.48)
Weighted average shares outstanding – basic and diluted	50,062	38,198	45,918	35,271

See the accompanying notes to these unaudited condensed financial statements.

Ignyta, Inc.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Six months ended June 30,	
	2017	2016
Operating activities:		
Net loss	$(68,438)	$(52,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
License fee obligation	12,846	—
Loss on debt extinguishment	—	696
Stock-based compensation	4,221	3,399
Depreciation and amortization of property and equipment	1,600	1,893
Amortization of premium on investment securities, net of accretion of discounts	97	465
Amortization of non-cash financing costs	321	260
Other	2,071	(671)
Increase (decrease) in cash resulting from changes in:		
Other current and long-term assets	376	(1,788)
Accounts payable, accrued expenses and other liabilities	(641)	(2,342)
Net cash used in operating activities	(47,547)	(50,230)
Investing activities:		
Purchases of investment securities	(67,937)	(99,782)
Maturities and sales of investment securities	68,260	89,523
Purchases of property and equipment	(206)	(1,056)
Proceeds from sale of property and equipment	37	—
Net cash provided by (used in) investing activities	154	(11,315)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	82,782	53,892
Proceeds from borrowings under term loan facility	—	17,116
Repayments of borrowings under term loan facility	—	(17,438)
Proceeds from exercise of stock options	1,512	399
Repayments under other long-term obligations	(94)	(89)
Net cash provided by financing activities	84,200	53,880
Net change in cash and cash equivalents	36,807	(7,665)
Cash and cash equivalents at beginning of period	24,340	46,383
Cash and cash equivalents at end of period	$61,147	$38,718
Supplemental disclosures of cash flow information:		
Cash paid for interest	$1,317	$1,551
Noncash investing and financing activities:		
Final payment obligation to Lenders recorded as debt discount (see note 6)	$-	$1,600
Unrealized gain on investment securities	$31	$312
Amounts capitalized under build-to-suit lease transaction	$-	$5,733

Interest capitalized during construction period for build-to-suit lease transaction	$-	$642

See the accompanying notes to these unaudited condensed financial statements.

Ignyta, Inc.

Notes to Unaudited Condensed Financial Statements

1. ORGANIZATION

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.

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.

Liquidity

The Company had negative cash flow from operations of approximately $47.5 million during the first six months of 2017 and, as of June 30, 2017, had an accumulated deficit of approximately $320.1 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 June 30, 2017, the Company had cash, cash equivalents and investment securities totaling approximately $169.4 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States 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, 2016, as filed with the SEC.

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. 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 facility with Silicon Valley Bank, as collateral agent ("SVB"), and Oxford Finance LLC ("Oxford" and collectively with SVB, the "Lenders"). 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.

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 the value of the term loan to fluctuate. The Company has not experienced any significant losses on its cash, cash equivalents, investment securities or its term loan. The Company's credit risk exposure is up to the extent of the value of its cash, cash equivalents and investment securities recorded on the Company's balance sheet.

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.

Clinical Trial and Pre-Clinical Study Accruals

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 as of each balance sheet date. 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.

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 share are 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 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.

The calculations of net loss per share excluded potentially dilutive securities (consisting of outstanding options, warrants, restricted stock and restricted stock units) of approximately 6.1 million and 5.6 million shares as of June 30, 2017 and 2016, respectively.

Recently Adopted Accounting Standards

In March 2016, the FASB issued ASU 2016-09, Compensation–Stock Compensation: 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. The Company adopted this standard on January 1, 2017. Adoption did not have a material impact on the Company's financial position or results of operations.

Recent Accounting Pronouncements

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. 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. This new standard is effective for the Company's fiscal year beginning January 1, 2019, and early adoption is permitted. The Company is evaluating the potential impact of this guidance on its financial statements and related financial statement disclosures.

In May 2017, the FASB issued ASU 2017-09, Stock Compensation (Topic 718), Scope of Modification Accounting. This ASU clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. This ASU will be effective for the Company's fiscal year beginning January 1, 2018, and is expected to impact modifications meeting the clarified criteria prospectively thereafter.

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 June 30, 2017			
	Amortized Gross	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
Commercial paper	$42,810	$ —	$ —	$42,810
Corporate debt securities	32,492	-	(16)	32,476
U.S. government and agency obligations	33,019	-	(74)	32,945
Total	$108,321	$ -	$ (90)	$108,231

As of December 31, 2016

	Amortized Gross	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale investment securities:				
Commercial paper	$8,996	$ —	$ —	$8,996
Corporate debt securities	49,179	1	(55)	49,125
U.S. government and agency obligations	50,568	1	(70)	50,499
Total	$108,743	$ 2	$ (125)	$108,620

All of the Company's available-for-sale investment securities held at June 30, 2017, had maturity dates of less than 24 months. The Company determines the appropriate designation of investment securities at the time of purchase and reevaluates such designation as of each balance sheet date. Securities classified as short-term investment securities have maturity dates of less than one year from the balance sheet date, while those classified as long-term investment securities 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. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented. 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 June 30, 2017. The Company reviewed its investment holdings as of June 30, 2017, 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.

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 June 30, 2017				As of December 31, 2016			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Investment securities:								
Commercial paper	$-	$42,810	$ —	$42,810	$-	$8,996	$ —	$8,996
Corporate debt securities	—	32,476	—	32,476	—	49,125	—	49,125
U.S. government and agency obligations	32,945	—	—	32,945	50,499	—	—	50,499
Total assets at fair value	$32,945	$75,286	$ —	$108,231	$50,499	$58,121	$ —	$108,620

5. BALANCE SHEET DETAILS

Property and Equipment

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

	June 30, 2017	December 31, 2016
Lab and manufacturing equipment	$ 6,333	$ 7,656
Office and computer equipment	2,078	1,762
Leasehold improvements	275	374
Property and equipment at cost	8,686	9,792
Accumulated depreciation and amortization	(4,011)	(3,522)
Property and equipment, net	$ 4,675	$ 6,270

Other Long-Term Liabilities

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

	June 30, 2017	December 31, 2016
Obligation due to licensor (note 7)	$ 6,387	$ —
Deferred rent	3,641	1,510
Final loan fee obligation to lender (note 6)	1,600	1,600
Other long-term liabilities	$ 11,628	$ 3,110

6. TERM LOAN FACILITY

In June 2016, the Company entered into a loan and security agreement (the “Loan Agreement”) with the Lenders. Under the Loan Agreement, 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 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% (8.35% at June 30, 2017) and have interest only payments for thirty months, followed by a principal amortization period of 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.

Future minimum principal payments of approximately $1.1 million commence in February 2019 and are due monthly through June 2021 as follows (in thousands):

Year ending December 31,	Minimum Principal Payments
2017 (6 months) and 2018	$ —
2019	11,733
2020	12,800
2021	7,467
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, including a prohibition on the payment of dividends. 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.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations of the Company under the Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such

collateral. In the event of default by the Company under the Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan Agreement, which could harm the Company's financial condition. The Company was in compliance with all of the covenants under the Loan Agreement as of June 30, 2017, and there had been no material adverse change.

7. 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 later amended on December 12, 2014. The license grants the Company exclusive global rights to develop and commercialize entrectinib. The Company's development rights under the license 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. 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 license agreement also requires that the Company make 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. Life-to-date payments to NMS in connection with this agreement totaled $17.0 million as of June 30, 2017, and included an up-front payment of $7.0 million (paid in November 2013) and an initial milestone payment of $10.0 million (paid in December 2014). All payments under this agreement have been expensed as research and development (as no future benefit was determined to exist at the time of payment).

RXDX-105 and RXDX-106

In connection with its 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 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.

Taladegib

The Company entered into a license, development and commercialization agreement with Eli Lilly and Company (“Lilly”) in November 2015, 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.

During the first quarter of 2017, the Company agreed to amend and restate the license, development and commercialization agreement (the "A&R License Agreement") with Lilly. Under the A&R License Agreement, the Company is obligated to pay to Lilly $15.0 million in four timing-based milestones, the first $3.0 million of which was paid in the first quarter of 2017. The remaining payments are payable in the first quarter of the subsequent three calendar years, subject to offsetting adjustment if the Company shall have received cash consideration in connection with an assignment, sale of the Licensed Products to a third party (other than in connection with the sale of substantially all of the assets of the Company), or grant of a sublicense prior to March 31, 2020. The Company recorded a charge of $12.8 million to research and development expense in the first quarter of 2017, which represented the net present value of the Company's obligation under the A&R License Agreement discounted at its incremental borrowing rate of 10.1%. The discount (of $2.2 million) will be accreted to research and development expense over 36 months.

The Company is obligated under the A&R License Agreement to use commercially reasonably efforts to develop the Licensed Products at its expense, provided, however, that if the Company is not actively developing the Licensed Products as of December 31, 2018, then the A&R License Agreement shall immediately terminate and the licenses granted to the Company shall terminate. The Company's timing-based milestone payment obligations under this amendment survive any such termination. When and if commercial sales of Licensed Products begin, the Company will be further 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. The A&R License Agreement also requires the Company to make sales-based milestone payments to Lilly of up to $20.0 million.

8. 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 $25.2 million as of June 30, 2017.

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 United States for its product candidates. The contracted cost under these arrangements totaled approximately $72.9 million as of June 30, 2017, of which approximately $38.9 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.

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 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 2017, the Company completed a public offering of an aggregate of 14,375,000 shares of its common stock for net proceeds of approximately $82.8 million (net of transaction costs of approximately $5.7 million).

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).

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 June 30, 2017, 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 June 30, 2017. These warrants have a weighted average exercise price of $5.75 per share and expire at various dates through June 2023.

10. 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 also has outstanding equity awards that were granted under certain predecessor plans. No additional equity grants may be made by the Company under any of these predecessor plans.

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, 2016	5,109,285	$ 8.86		
Granted	996,769	$ 5.76		
Exercised	(197,136)	$ 7.67		
Forfeited and expired	(176,699)	$ 14.12		

Balance at June 30, 2017	5,732,219	$ 8.20	7.9	$ 14,830
Exercisable at June 30, 2017	2,769,424	$ 8.25	7.1	$ 7,156

As of June 30, 2017, an aggregate of 2,565,595 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 six months of 2017 and 2016 was $3.94 and $5.62 per share, respectively, and was estimated using the following weighted-average assumptions:

	Fiscal 2017	Fiscal 2016
Expected life of option	6.2. years	5.9 years
Volatility	78%	72%
Risk free interest rate	2.0%	1.4%
Dividend yield	—%	—%

Stock-Based Compensation

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Included in research and development	$1,608	$805	$2,638	$1,621
Included in general and administrative	684	894	1,583	1,778
Total	$2,292	$1,699	$4,221	$3,399

Unrecognized stock-based compensation expense related to unvested awards granted under the Company’s equity incentive plans totaled $13.7 million as of June 30, 2017, and is expected to be recognized over a weighted-average period of 2.4 years.

Restricted Stock Units

Under the provisions of its equity incentive plan, the Company may issue restricted stock units to members of its board of directors or its employee team. As of June 30, 2017, an aggregate of 231,520 restricted stock units were outstanding and subject to vesting through January 2021.

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 included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, 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, 2016. 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, 2016, 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.

Overview

We are a biotechnology company focused on precision medicine in oncology. 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, CNS-active, small molecule tyrosine kinase inhibitor directed to the TRK (tropomyosin receptor kinase) family tyrosine kinase receptors (TRKA, TRKB and TRKC), ROS1 and ALK (anaplastic lymphoma kinase) 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 a Phase 1/1b clinical study in pediatric patients with advanced solid tumor malignancies;
- RXDX-105, an orally bioavailable, small molecule tyrosine kinase inhibitor of RET that spares the vascular endothelial growth factor receptor, or VEGFR, which has achieved clinical proof-of-concept and is in an ongoing Phase 1b clinical trial;
- 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; and
- RXDX-106, a small molecule, potent immunomodulating inhibitor of TYRO3, AXL and MER, or collectively TAM, 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 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; and we acquired exclusive, global development and commercialization rights to taladegib under a license agreement with Eli Lilly and Company, or Lilly, in November 2015, which agreement was subsequently amended and restated in March 2017. In connection with such amendment and restatement, we announced our intention to explore strategic options for the taladegib program in basal cell carcinoma.

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 discovery, and developing drug 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 the development of our product candidates and our biomarker discovery efforts, 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 periodic 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:

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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;
- 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;

- the availability of adequate reimbursement and pricing by third-party payers and government authorities;
- establishing commercial manufacturing and distribution 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 and our biomarker discovery efforts 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 costs related to operating as a public company, 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.

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, 2016. There have not been any material changes to our critical accounting policies since December 31, 2016.

Recently Adopted Accounting Standards

In March 2016, the FASB issued ASU 2016-09, Compensation–Stock Compensation: 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. We adopted this standard on January 1, 2017. Adoption did not have a material impact on our financial position or results of operations.

Recent Accounting Pronouncements

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. 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. This new standard is effective for our fiscal year beginning January 1, 2019, and early adoption is permitted. We are evaluating the potential impact of this guidance on its financial statements and related financial statement disclosures.

In May 2017, the FASB issued ASU 2017-09, Stock Compensation (Topic 718), Scope of Modification Accounting. This ASU clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. This ASU will be effective for our fiscal year beginning January 1, 2018, and is expected to impact modifications meeting the clarified criteria prospectively thereafter.

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the three months ended June 30, 2017 and 2016, together with the changes in those items in dollars (in thousands) and as a percentage:

	Three months ended June 30,		Dollar	Percentage
	2017	2016	Change	Change
Operating expenses:				
Research and development	$ 22,172	$ 20,019	$2,153	11%
General and administrative	5,496	5,499	(3)	0%
Total operating expenses	27,668	25,518	2,150	8%
Loss from operations	(27,668)	(25,518)	(2,150)	8%
Other income (expense), net	(610)	(1,132)	522	-46%
Net loss	$ (28,278)	$ (26,650)	$(1,628)	6%

Research and Development Expense. Research and development (“R&D”) expenses increased by $2.2 million during 2017 as compared to the same period in 2016, an increase of 11%. This increase was due to an increase in external clinical development and chemistry, manufacturing and control costs associated with the development of entrectinib and our other product candidates. We also incurred increased facilities costs of $1.2 million, due to the expansion of our leased facilities space, and additional stock compensation costs of $0.8 million, due in part to the increase in the number of outstanding stock options.

General and Administrative Expense. There was no measurable change in our general and administrative expenses during 2017 in comparison to the same period in 2016, as the increase in facilities costs, due to the expansion of our leased facilities, and the increase in outside services expenses, due to an increase in pre-launch commercial activities, was offset by a reduction in our personnel related expenditures.

Comparison of the Six Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for the six months ended June 30, 2017 and 2016, together with the changes in those items in dollars (in thousands) and as a percentage:

	Six months ended June 30, 2017	2016	Dollar Change	Percentage Change
Operating expenses:				
Research and development	$ 56,218	$ 39,800	$16,418	41%
General and administrative	11,065	10,726	339	3%
Total operating expenses	67,283	50,526	16,757	33%
Loss from operations	(67,283)	(50,526)	(16,757)	33%
Other income (expense), net	(1,155)	(1,616)	461	-29%
Net loss	$ (68,438)	$ (52,142)	$(16,296)	31%

Research and Development Expense. R&D expenses increased by $16.4 million during 2017 as compared to the same period in 2016, an increase of 41%. This increase was primarily due to the $12.8 million charge recorded in the first quarter of 2017 in connection with the amendment and restatement of our license, development and commercialization agreement with Lilly. Fiscal 2017 R&D costs also include increased facilities costs of $2.4 million, due to the expansion of our leased facilities space, and additional stock compensation costs of $1.0 million, due in part to the increase in the number of outstanding stock options.

General and Administrative Expense. General and administrative expenses increased by $0.3 million during 2017 as compared to the same period in 2016, an increase of 3%. The increase in general and administrative expenses was attributable to an increase in our facilities costs.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, and through June 30, 2017, we have raised an aggregate of approximately $442.2 million to fund our operations, of which approximately $88.4 million was received from our issuance and sale of our common stock in an underwritten public offering in May 2017, $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 and security agreement, or 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 the issuance of common stock upon the exercise from time to time of stock options.

Public Offerings. In May 2017, May 2016, June 2015 and March 2014, we issued an aggregate of 33,892,464 shares of our common stock in underwritten public offerings. All of the shares issued in the May 2017 offering were sold at a purchase price per share to the public of $6.15, all of the shares issued in the May 2016 offering were sold at a purchase price per share to the public of $6.25, all of the shares issued in the June 2015 offering were sold at a purchase price per share to the public of $17.50, and all of the shares issued in the March 2014 offering were sold at a purchase price per share to the public of $9.15. The offerings generated aggregate gross proceeds of approximately $276.1 million and aggregate net proceeds, after deducting underwriting discounts and commissions and other offering fees and expenses, of approximately $258.3 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% (8.35% at June 30, 2017). Monthly principal payments of approximately $1.1 million commence in February 2019 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 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

Comparison of cash flows for the six months ended June 30, 2017 and 2016

The following table provides information regarding our cash flows during the six months ended June 30, 2017 and 2016 (in thousands):

	Six months ended June 30,	
	2017	2016
Net cash used in operating activities	$ (47,547)	$ (50,230)
Net cash provided by (used in) investing activities	154	(11,315)
Net cash provided by financing activities	84,200	53,880
Net change in cash and cash equivalents	$ 36,807	$ (7,665)

Net Cash Used in Operating Activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Such activities resulted in a net use of funds of approximately $47.5 million during 2017 compared to approximately $50.2 million used during the same period in 2016.

Net Cash Provided by (used in) Investing Activities. Investing activities represent investment activity associated with our investment securities and, to a lesser extent, the cash outflow associated with purchases of fixed assets. Such activities resulted in a net increase of funds of approximately $0.2 million during 2017, while our investing activities used net cash of approximately $11.3 million during the same period in 2016.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was approximately $84.2 million during 2017, compared to approximately $53.9 million provided by financing activities during the same period of 2016. Cash provided by financing activities during both periods was primarily the result of the funds raised through sales of our common stock.

Funding Requirements

We expect our expenses to continue to increase in the future in connection with 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, some of which may be incurred in advance of such marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborators with whom we may engage.

As of June 30, 2017, we had approximately $169.4 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;
- 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;
    - the availability of adequate reimbursement and pricing by third-party payers and government authorities;
- 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.

Cautionary Note 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 termi
Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with 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; our ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of our product candidates; changes in our plans to develop and commercialize our product candidates; the potential for final results of the ongoing clinical trials of entrectinib or other product candidates, or any future clinical trials of entrectinib or other product candidates, to differ from preliminary or expected results; the early stage of our product candidates presently under development; our need for additional funds in order to pursue our business plan and the uncertainty of whether we will be able to obtain the funding we need; our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates, and any future product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate; our ability to retain or hire key scientific or management personnel; our ability, potentially with partners, to validate, develop and obtain regulatory approval of companion diagnostics for our product candidates; our ability to obtain and maintain intellectual property protection for our product candidates, including patent and other intellectual property rights; the risk that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained;

the potential for us to fail to maintain the CAP accreditation and CLIA certification of our diagnostic laboratory; the loss of key scientific or management personnel; competition in the industry in which we operate; 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; 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.

We also have a loan arrangement with SVB and Oxford under which we have borrowed $32.0 million, which accrues interest at a variable rate equal to the Prime Rate plus 4.35% (8.35% at June 30, 2017). A 1.0% change in the Prime Rate occurring on June 30, 2017 would change our interest costs by approximately $0.7 million over the remaining contractual term 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 2017 or 2016.

Item 4. Controls and Procedures

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

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2017 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, 2016 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, 2016, other than as previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, 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, 2016 was $103.6 million, and our net loss for the six months ended June 30, 2017 was $68.4 million. As of June 30, 2017, we had an accumulated deficit of $320.1 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are currently focused on the development of our clinical and preclinical development programs, which we believe will result in our continued incurrence of significant research and development and other expenses related to those programs. If the non-clinical or clinical trials for any of our product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We expect to need additional funding to continue our operations, which could result in dilution or restrictions on our business activities. We may not be able to raise capital when needed, if at all, which would force us to delay, limit, reduce or terminate our product development programs or commercialization efforts and could cause our business to fail.

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

Even after giving effect to the proceeds received from our public offering of common stock that was consummated in May 2017, our other common stock offerings and our loan arrangement with SVB and Oxford, we expect to require substantial additional capital for the further development and commercialization of our product candidates. Further, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to expand our ongoing entrectinib and other development programs, and if we acquire rights to additional product candidates. For example, in September 2015 we initiated a new, global Phase 2 clinical trial of oral entrectinib in adult patients with advanced or metastatic cancer detected to be positive for relevant molecular alterations. We are conducting and plan to initiate additional clinical trials to study our other product candidates in the future.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with our growth, as well as operating as a public company. For example, in October 2015 we signed a new lease for approximately 95,000 square feet of office and laboratory space, which lease became effective in the fourth quarter of 2016. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs

and/or cause us to spend our cash resources faster than we expect. Accordingly, we expect to need to obtain substantial additional funding in order to continue our operations.

To date, we have financed our operations entirely through equity investments and the incurrence of debt, and we expect to continue to do so in the foreseeable future. We may also seek funding through collaborative arrangements. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders, which could be significant depending on the price at which we may be able to sell our securities. If we raise additional capital through the incurrence of further indebtedness, as we have done under our loan agreement with SVB and Oxford under which our ability to incur additional indebtedness is limited, we would likely become subject to additional covenants restricting our business activities, and holders of debt instruments may have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal

repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technology or product candidates and could result in our receipt of only a portion of the revenues associated with the partnered products. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts. Any of these events could significantly harm our business, financial condition and prospects.

We have incurred significant indebtedness under our loan agreement with SVB and Oxford, which will require substantial cash to service and which subjects our business to certain restrictions.

On June 30, 2016, we entered into a loan agreement with SVB as collateral agent and SVB and Oxford, collectively referred to as the Lenders, under which we incurred $32.0 million of indebtedness, substantially all of which was used to repay our then-existing $31.0 million loan with SVB. Under the loan agreement, we also have an option to receive an additional $10.0 million at any time from April 7, 2017 to August 31, 2017, provided that certain conditions have then been satisfied. We are required to pay interest on the borrowings under the loan agreement at a per-annum rate of Prime Rate plus 4.35% on a monthly basis for a period of 30 months. Thereafter, we will be required to repay the principal plus interest in 30 equal monthly installments. Further, upon the maturity date the terms of the loan agreement require that we make a final lump-sum payment of 5% of the principal amount of the loans thereunder. We may elect to prepay all amounts owed under either or both of the loan tranches prior to the maturity date therefor, provided that a prepayment fee of 2% of the amount prepaid is also paid if the prepayment occurs on or prior to June 30, 2017, or 1% of amount prepaid is also paid, if the prepayment occurs thereafter.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time.

We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. Additionally, the loan agreement contains various covenants, including an obligation to deliver to the Lenders certain financial and insurance information and comply with certain notice requirements, and covenants that restrict our ability, without prior consent, to: incur certain additional indebtedness, enter into certain mergers, acquisitions or other business combination transactions, or incur any non-permitted lien or

other encumbrance on our assets. Any failure by us to comply with any of those covenants, subject to certain cure periods, or to make all payments under the loan agreement when due, would cause us to be in default. In the event of any such default, the Lenders may be able to declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all or substantial amounts of our available cash to be used to repay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

Risks Related to the Development of Our Product Candidates

We may not be able to obtain orphan drug exclusivity for the product candidates for all indications for which we seek or receive regulatory approval, which could limit the potential profitability of such product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it receives the designation, then the product is entitled to a period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same drug for the exclusivity period for the same indication, except in limited situations.

The FDA has granted us orphan drug designation for entrectinib for (i) treatment of NTRK fusion-positive solid tumors, and (ii) the treatment of TRKA-positive, TRKB-positive, TRKC-positive, ROS1-positive or ALK-positive non-small cell lung cancer and colorectal cancer. We have also received orphan drug designation from the FDA and the EMA for entrectinib for the treatment of neuroblastoma. We expect that we may in the future pursue orphan drug designations for entrectinib in other jurisdictions and/or indications, and for at least some of our other product candidates. Obtaining orphan drug designations can be difficult and we may not be successful in doing so. In addition, orphan drug exclusivity may not effectively protect a product from the competition of different drugs for the same indication, which could be approved during the exclusivity period. Further, after an orphan designated drug is approved and if it obtains orphan drug exclusivity, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. The failure to obtain an orphan drug designation for any product candidates for rare cancer indications for which we seek or receive regulatory approval, and/or the inability to maintain that designation for the duration of the applicable exclusivity period, could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

A Breakthrough Therapy Designation, Fast Track Designation or accelerated approval by the FDA may not actually lead to a faster development or regulatory review or approval process for any of our product candidates.

In May 2017, we received breakthrough therapy designation for entrectinib for the treatment of NTRK fusion-positive, locally advanced or metastatic solid tumors in adult and pediatric patients who have either progressed following prior therapies or who have no acceptable standard therapies. Additionally, we may in the future seek a breakthrough therapy designation for entrectinib in other indications, or for certain of our other product candidates. The Food and Drug Administration Safety and Innovation Act established the breakthrough therapy designation for drugs intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and may determine not to grant such a designation. Even if we receive a breakthrough therapy designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Further, obtaining a breakthrough therapy designation does not assure or

increase the likelihood of the FDA's approval of the applicable product candidate. In addition, even if one or more of our product candidates qualifies as a breakthrough therapy, the FDA could later determine that those products no longer meet the conditions for the designation or determine not to shorten the time period for FDA review or approval.

We may also in the future seek fast track designation for some of our product candidates that reach the regulatory review process. If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply to the FDA for a fast track designation for the product candidate. If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In addition, a fast track product may be eligible for accelerated approval, as described below. The FDA has broad discretion over whether to grant a fast track designation and, as a result, even our product candidates that may be eligible for such a designation may not receive it. Even if we were to receive fast track designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Additionally, the FDA could withdraw a fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also in the future seek accelerated approval for some of our product candidates. Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening disease or condition that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or sooner than clinical endpoints. As with fast track designation and breakthrough therapy designation, the FDA has broad discretion over whether to grant approval based on a surrogate endpoint. Accordingly, even if we believe one of our product candidates meets the criteria for accelerated approval, the FDA may disagree and may determine not to grant such approval.

In addition, a product candidate approved on such an accelerated basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate the surrogate endpoint or otherwise confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis.

Risks Related to Managing Any Growth We May Experience

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

As of June 30, 2017, we had 118 employees, 114 of whom were full-time and four of whom were part-time employees. As our development and commercialization plans and strategies develop, we expect to need additional research, development, managerial, operational, sales, marketing, financial, accounting, legal and other resources. We expect future growth to impose significant added responsibilities on members of management, particularly as we continue to expand our ongoing entrectinib and other development programs including:

- effectively managing our clinical trials and submissions to regulatory authorities for marketing approvals;
- effectively managing our preclinical development efforts;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- establishing relationships with third parties essential to our business and ensuring compliance with our contractual obligations to such third parties;
-

developing and managing new segments of our internal business, including any sales, marketing and commercial operations functions we may elect to establish;

- maintaining our compliance with public company reporting and other obligations, including establishing and maintaining effective internal control over financial reporting and disclosure controls and procedures; and
- improving our managerial, development, operational and finance systems. We may not be able to accomplish any of those tasks, and our failure to do so could prevent us from effectively managing future growth, if any, and successfully growing our company.

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 July 31, 2017, a total of 56,253,915 shares of our common stock were outstanding. Of those shares, approximately 51,942,680 were freely tradable, without restriction, in the public market. Such shares represented approximately 92.3% 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 July 31, 2017, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 30.1% of our outstanding voting stock (which includes shares they had the right to acquire within 60 days). Accordingly, our directors and executive officers and holders of 5% or more of our capital stock 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).

Exhibit Number	Description of Exhibit
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a –14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a –14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

*Filed herewith.

SIGNATURES

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

IGNYTA, INC.

Date: August 8, 2017 By: /s/ Jonathan E. Lim, M.D.
Jonathan E. Lim, M.D.
President and Chief Executive Officer

Date: August 8, 2017 By: /s/ Jacob M. Chacko, M.D.
Jacob M. Chacko, M.D.
Chief Financial Officer