Sorrento Therapeutics, Inc.
Form 10-Q
November 16, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

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

Commission file number 001-36150

SORRENTO THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	33-0344842
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

9380 Judicial Drive,

San Diego, California 92121

(Address of Principal Executive Offices)

(858) 210-3700

(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 x 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 x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of shares of the issuer's common stock, par value $0.0001 per share, outstanding as of November 9, 2015 was 37,767,085.

Sorrento Therapeutics, Inc.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.
SORRENTO THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except for share amounts)

	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,067	$ 71,902
Marketable securities	64,386	—
Grants and accounts receivables, net	622	732
Prepaid expenses and other, net	731	1,281
Total current assets	124,806	73,915
Property and equipment, net	3,813	2,277
Intangibles, net	4,023	4,357
Goodwill	20,626	24,041
Investments in common stock	111,500	10,000
Equity method investments	60,000	—
Long-term assets held for sale	—	26,619
Other, net	527	332
Total assets	$ 325,295	$ 141,541
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,619	$ 1,656
Accrued payroll and related	1,683	1,825
Current portion of deferred compensation	973	1,893
Accrued expenses	3,215	867
Acquisition consideration payable	13,855	—
Current portion of debt	4,722	3,316
Total current liabilities	26,067	9,557
Long-term debt	5,646	8,830
Deferred compensation	877	796
Deferred tax liabilities	34,507	1,709
Long-term liabilities held for sale	—	10,837
Deferred revenue	110,912	1,024
Deferred rent and other	501	75
Total liabilities	178,510	32,828
Commitments and contingencies		
Equity:		
Sorrento Therapeutics, Inc. equity		

Preferred stock, $0.0001 par value; 100,000,000 shares authorized and no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 750,000,000 shares authorized and 37,767,085 and 36,184,912 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	4	4
Additional paid-in capital	181,652	176,227
Accumulated other comprehensive income	54,386	—
Accumulated deficit	(89,853)	(67,518)
Total Sorrento Therapeutics, Inc. stockholders' equity	146,189	108,713
Noncontrolling interests	596	—
Total equity	146,785	108,713
Total liabilities and equity	$ 325,295	$ 141,541

See accompanying unaudited notes

SORRENTO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Grant	$367	$147	$1,064	$329
Sales and services	736	1,129	2,189	2,698
Total revenues	1,103	1,276	3,253	3,027
Operating costs and expenses:				
Costs of revenues	604	527	1,427	1,600
Research and development	7,244	5,440	23,055	16,856
Acquired in-process research and development	24,068	—	24,068	209
General and administrative	4,711	1,854	10,002	7,600
Intangible amortization	111	586	1,046	1,758
Total costs and operating expenses	36,738	8,407	59,598	28,023
Loss from operations	(35,635)	(7,131)	(56,345)	(24,996)
Gain on sale of IgDraSol, net	69,274	—	69,274	—
Interest expense	(396)	(476)	(1,277)	(1,167)
Interest income	1	2	1	11
Income (loss) before income tax expense	33,244	(7,605)	11,653	(26,152)
Income tax expense	35,323	—	35,128	—
Net loss	(2,079)	(7,605)	(23,475)	(26,152)
Net loss attributable to noncontrolling interests	(1,140)	—	(1,140)	—
Net loss attributable to Sorrento	$(939)	$(7,605)	$(22,335)	$(26,152)
Net loss per share - basic and diluted per share attributable to Sorrento	$(0.03)	$(0.27)	$(0.61)	$(1.02)
Weighted-average shares used during period - basic and diluted per share attributable to Sorrento	37,328	28,533	36,618	25,682

See accompanying unaudited notes

SORRENTO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss attributable to Sorrento	$(939)	$(7,605)	$(22,335)	$(26,152)
Other comprehensive income:				
Unrealized gains on marketable securities	54,386	—	54,386	—
Total other comprehensive income	54,386	—	54,386	—
Comprehensive income (loss) attributable to Sorrento	53,447	(7,605)	32,051	(26,152)
Comprehensive income (loss) attributable to noncontrolling interests	—	—	—	—
Comprehensive income (loss)	$53,447	$(7,605)	$32,051	$(26,152)

See accompanying unaudited notes

SORRENTO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(23,475)	$(26,152)
Adjustments to reconcile net loss to net cash provided by and (used in) operating activities:		
Depreciation and amortization	1,837	2,372
Non-cash interest expense	298	331
Gain on sale of IgDraSol	(69,274)	—
Stock-based compensation	5,483	3,159
Acquired in-process research and development	13,855	209
Provision for doubtful accounts	4	9
Deferred tax provision	32,798	—
Changes in operating assets and liabilities; net of acquisitions:		
Grants and other receivables	106	(601)
Prepaid expenses and other	293	(254)
Accounts payable	(352)	(703)
Deferred revenue	9,888	—
Accrued expenses and other liabilities	2,632	522
Net cash used for operating activities	(25,907)	(21,108)
Investing activities		
Purchases of property and equipment	(1,950)	(433)
Proceeds from sale of IgDraSol	27,759	—
Investments in common stock	(11,500)	—
Net cash provided by (used in) investing activities	14,309	(433)
Financing activities		
Net borrowings under loan and security agreement	—	7,500
Proceeds from issuance of common stock, net of issuance costs and repurchases	—	26,643
Net principal payments under loan and security agreement	(1,915)	—
Net payments of deferred compensation	(1,000)	—
Proceeds from exercise of stock options	1,678	—
Net cash (used in) provided by financing activities	(1,237)	34,143
Net change in cash and cash equivalents	(12,835)	12,602
Cash and cash equivalents at beginning of period	71,902	31,667
Cash and cash equivalents at end of period	$59,067	$44,269
Supplemental disclosures:		
Cash paid during the period for:		
Income taxes	$3	$6
Interest paid	$720	$636

Supplemental disclosures of non-cash investing and financing activities:		
Change in unrealized gains (losses) on marketable securities	$54,386	$—
Increase in cost method investment in deferred revenue	$(100,000)	$—
Contributions to equity method investments made on Company's behalf	$(60,000)	$—
Property and equipment costs incurred but not paid	$315	$—
Issuance of 1,306,272 shares to former stockholders of IgDraSol	$—	$—

See accompanying unaudited notes

SORRENTO THERAPEUTICS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2015

(In thousands, except for share amounts)

1. Nature of Operations, Summary of Significant Accounting Policies and Business Activities

Nature of Operations and Basis of Presentation

Sorrento Therapeutics, Inc. (NASDAQ: SRNE), together with its subsidiaries (collectively, the "Company") is a biopharmaceutical company focused on the discovery, acquisition, development and commercialization of proprietary therapeutic products for addressing significant unmet medical needs worldwide. The Company's primary therapeutic focus is oncology, including the treatment of chronic cancer pain, but is also developing therapeutic products for other indications, including immunology and infectious diseases. The Company currently has multiple clinical development programs underway: CAR-T programs for solid tumors, resiniferatoxin, or RTX, a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for intractable pain in end-stage disease and its clinical development program for its biosimilar/biobetter antibodies that the Company licensed from Mabtech Limited, a holding company for antibody development and manufacturing companies in China. On July 8, 2015, the Company consummated the previously announced sale to NantPharma, LLC, a related party, of all of the Company's equity interests in IgDraSol, Inc., a wholly-owned subsidiary of the Company which holds all the rights to Cynviloq, a polymeric micelle based Cremophor free paclitaxel injectable finished formulation.

The Company's pipeline also includes preclinical fully human therapeutic monoclonal antibodies (mAbs) such as its fully human anti-PD-L1 and anti-PD-1 checkpoint inhibitors derived from its proprietary G-MAB® library platform, antibody drug conjugates (ADCs), bispecific antibodies (BsAbs), as well as Chimeric Antigen Receptor-T Cell (CAR-T) and Chimeric Antigen Receptor Tumor-attacking Neukoplast® (CAR.TNK™, pronounced "CARTANK") for adoptive cellular immunotherapies (ACI). The Company's objective is to develop its antibody drug products and adoptive cellular immunotherapies as: (i) First in Class (FIC), and/or (ii) Best in Class (BIC), which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs, as well as fully human therapeutic antibodies derived from its proprietary G-MAB® library platform and antibody drug conjugates, or ADCs.

Through September 30, 2015, the Company had devoted substantially all of its efforts to research and product development, raising capital and building infrastructure, and had not realized revenues from its planned principal operations.

The accompanying interim consolidated financial statements have been prepared by the Company, without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair statement of its financial position, results of operations and cash flows in accordance with United States generally accepted accounting principles (GAAP). The accompanying consolidated financial statements include the accounts of the Company's wholly-owned subsidiaries and those of a variable interest entity where the Company is the primary beneficiary. For consolidated entities where the Company owns or are exposed to less than 100% of the economics, the Company records net income (loss) attributable to noncontrolling interests in its consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. Two subsidiaries, Sorrento Therapeutics, Inc. Hong Kong Limited and Scintilla Pharmaceuticals, Inc., had no operating activity through September 2015. All intercompany balances and transactions have been eliminated in consolidation.

In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. These considerations impact the way the Company accounts for its existing collaborative relationships and other arrangements. The Company continuously assesses whether it is the primary beneficiary of a variable interest entity as changes to existing relationships or future transactions may result in the Company consolidating or deconsolidating one or more of its collaborators or partners.

The balance sheet at December 31, 2014 is derived from the audited consolidated financial statements at that date which are not presented herein.

In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of financial position, results of operations and cash flows. These consolidated financial statements should be read in conjunction with the consolidated financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014. Operating results for interim periods are not expected to be indicative of operating results for the Company’s 2015 fiscal year.

Liquidity

The Company anticipates that it will continue to incur net losses into the foreseeable future as it (i) advances clinical stage product candidates such as BioSimilar/BioBetter antibodies, CAR-T programs and RTX in the clinic and potentially pursues other development, (ii) continues to identify a number of potential mAb and ADC drug candidates and further advances various preclinical and development activities, (iii) advances its product candidates into the clinic, (iv) invests in additional joint ventures or third party collaboration or acquisition agreements, and (v) expands corporate infrastructure, including the costs associated with being a NASDAQ listed public company. Based on currently available resources, the Company believes it has the ability to meet all obligations due over the course of the next twelve months.

In June 2015, the National Institutes of Health, or NIH announced that the Clinical Center suspended operations of its Pharmaceutical Development Section after FDA inspections that occurred in May 2015. An FDA inspection report issued on May 29, 2015 noted “deficiencies in the physical facility, including flaws in the air handling system, and operational failures including inadequate quality control, insufficient employee training, and lack of compliance with standard operating procedures”. As a result, 46 clinical programs, including the resiniferatoxin (RTX) study in patients with severe pain in advanced cancer, were placed on clinical hold by the FDA. NIH has developed an interim corrective action/preventative action plan which has not yet been approved by the FDA. The Company plans to continue with its already planned corporate IND for RTX.

In August 2015, the Company and TNK Therapeutics, Inc., (“TNK”), a subsidiary of the Company, entered into a Membership Interest Purchase Agreement (the “Membership Interest Purchase Agreement”) with CARgenix Holdings LLC (“CARgenix”) and the members of CARgenix (the “Members”) pursuant to which the Members sold all of their membership interests in CARgenix to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A common stock, subject to adjustment in certain circumstances, to be issued to the Members upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a “Qualified Financing”). In the event a Qualified Financing does not occur by March 15, 2016 or TNK does not complete an initial public offering of shares of its capital stock by March 31, 2016, in lieu of receiving shares of TNK pursuant to the acquisition, the Members shall receive an aggregate of 309,917 shares of common stock of the Company, subject to adjustment in certain circumstances. The Membership Interest Purchase Agreement further provides that 20% of the shares of TNK or the Company, as applicable, issuable to the Members shall be held in escrow to secure certain post-closing adjustment and indemnification rights of TNK for a period of 12 months following the closing of the transaction.

In August 2015, the Company and TNK entered into a Stock Purchase Agreement (the “Stock Purchase Agreement”) with BDL Products, Inc. (“BDL”) and the stockholders of BDL (“Stockholders”) pursuant to which the Stockholders sold all of their shares of capital stock in BDL to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A common stock, subject to adjustment in certain circumstances, to be issued to the Stockholders upon a Qualified Financing. In the event a Qualified Financing does not occur by March 15, 2016 or TNK does not complete an initial public offering of shares of its capital stock by March 31, 2016, in lieu of receiving shares of TNK pursuant to the acquisition, the Stockholders shall receive an aggregate of 309,917 shares of common stock of the Company, subject to adjustment in certain circumstances. The Stock Purchase Agreement further provides that 20% of the shares of TNK or the Company, as applicable, issuable to the Stockholders shall be held in escrow to secure certain post-closing adjustment and indemnification rights of TNK for a period of 12 months following the closing of the transaction.

In August 2015, the Company entered into an exclusive licensing agreement to develop and commercialize multiple prespecified biosimilar or biobetter antibodies from Mabtech Limited. Under the terms of the agreement, the Company will develop and market these four monoclonal antibodies (mAbs) for the North American, European and Japanese market. The Company made an initial license payment of $10.0 million which was recognized as acquired in-process research and development expense in the consolidated statements of operations. The agreement includes

additional milestone payments totaling up to $190.0 million payable over the next five years.

In April 2015, the Company and NantCell, Inc. (“NantCell”) established a new joint venture called Immunotherapy NANTibody, LLC, or NANTibody, as a stand-alone biotechnology company with $100.0 million initial joint funding. NantCell owns 60% of the equity interest of NANTibody and agreed to contribute $60.0 million to NANTibody. The Company owns 40% of NANTibody and in July 2015 the Company had NantPharma contribute its portion of the initial joint funding of $40 million to NANTibody from the proceeds of the sale of IgDraSol. NANTibody will focus on accelerating the development of multiple immuno-oncology monoclonal antibodies (mAbs) for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-check point antibodies as well as antibody drug conjugates (ADCs) and bispecific antibodies.

NANTibody had no significant operations and incurred minimal general and administrative expenses during the three and nine months ended September 30, 2015.

In July 2015, the Company and NantBioScience established a new joint venture called NantCancerStemCell, LLC, or NantStem, as a stand-alone biotechnology company with $100 million initial joint funding. As initially organized, NantBioScience was obligated to make a $60 million cash contribution to NantStem for a 60% equity interest in NantStem, and the Company was obligated to make

a $40 million cash contribution to NantStem for a 40% equity interest in NantStem. Fifty percent of these contributions were funded in July 2015 and the remaining amounts were to be made by no later than September 30, 2015. The Company had NantPharma contribute its portion of the initial joint funding of $20 million to NantStem from the proceeds from the sale of IgDraSol. Pursuant to a Side Letter dated October 13, 2015, the NantStem joint venture agreement was amended to relieve the Company of the obligation to contribute the second $20 million payment, and the Company's ownership interest in NantStem was reduced to 20%. NantBioScience's funding obligations were unchanged. The Side Letter was negotiated at the same time the Company issued a call option on shares of NantKwest that it owned to Cambridge Equities, LP, a related party to the Company and to NantBioScience. See Note 13.

The Company plans to continue to fund its operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. The Company filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission ("SEC"), which was declared effective by the SEC in July 2013. The Shelf Registration Statement provides the Company the ability to offer up to $100 million of securities, including equity and other securities as described in the registration statement. After the May 2014 underwritten offering the Company has the ability to offer up to $36.6 million of additional securities under the July 2013 registration statement. In November 2014, the Company filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC in December 2014. This Shelf Registration Statement provides the Company with the ability to offer up to $250 million of securities, including equity and other securities as described in the registration statement. Included in the 2014, shelf registration is a sales agreement prospectus covering the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $50.0 million of the Company's common stock that may be issued and sold under a sales agreement with MLV & Co. LLC. The Company cannot be sure that such additional funds will be available on reasonable terms, or at all. If the Company is unable to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, and future prospects

If the Company raises additional funds by issuing equity securities, substantial dilution to existing stockholders would 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 covenants that may restrict the Company's ability to operate its business.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company minimizes its credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. The Company has not experienced any losses on such accounts.

Fair Value of Financial Instruments

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair

value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

· Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

· Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

· Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its

entirety requires it to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of our financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable and payable, and other financial instruments in current assets or current liabilities.

Marketable Securities

Marketable securities are designated as available-for-sale securities and are accounted for at fair value. Marketable securities are classified as short-term or long-term based on the nature of the securities and their availability to meet current operating requirements. Marketable securities that are readily available for use in current operations are classified as short-term available-for-sale securities and are reported as a component of current assets in the accompanying consolidated balance sheets. Marketable securities that are not considered available for use in current operations are classified as long-term available-for-sale securities and are reported as a component of long-term assets in the accompanying consolidated balance sheets.

Securities that are classified as available-for-sale are carried at fair value, with temporary unrealized gains and losses reported as a component of stockholders' equity until their disposition. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on its then current intent and ability to sell the security if it is required to do so. The cost of securities sold is based on the specific identification method.

All of the Company’s marketable securities are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. For the three and nine months ended September 30, 2015, no other-than-temporary impairment charges were recorded.

Grants and Accounts Receivable

Grants receivable at September 30, 2015 and December 31, 2014 represent amounts due under several federal contracts with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, or NIH, collectively, the NIH Grants. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

Accounts receivable at September 30, 2015 and December 31, 2014 consists of trade receivables from sales and services provided to certain customers, which are generally unsecured and due within 30 days. Estimated credit losses related to trade accounts receivable are recorded as general and administrative expenses and as an allowance for doubtful accounts within grants and accounts receivable, net. The Company reviews reserves and makes adjustments based on historical experience and known collectability issues and disputes. When internal collection efforts on accounts have been exhausted, the accounts are written off by reducing the allowance for doubtful accounts. As of September 30, 2015 and December 31, 2014, the allowance for doubtful accounts was $4 and $33, respectively.

Property and Equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are amortized over the lesser of the life of the lease or the life of the asset. Repairs and

maintenance are charged to expense as incurred.

Acquisitions and Intangibles

The Company has engaged in business combination activity. The accounting for business combinations requires management to make judgments and estimates of the fair value of assets acquired, including the identification and valuation of intangible assets, as well as liabilities assumed. Such judgments and estimates directly impact the amount of goodwill recognized in connection with each acquisition, as goodwill presents the excess of the purchase price of an acquired business over the fair value of its net tangible and identifiable intangible assets.

Goodwill and Other Long-Lived Assets

Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. Goodwill is reviewed for impairment at least annually during the fourth quarter, or more frequently if events occur indicating the potential for impairment. During its goodwill impairment review, the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, the Company determines that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the Company proceeds to perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair value of the reporting unit with its carrying value, including goodwill. If the carrying amount of the reporting unit exceeds its fair value, the Company performs the second step of the goodwill impairment test to determine the amount of loss, which involves comparing the implied fair value of the goodwill to the carrying value of the goodwill. The Company may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the first step of the goodwill impairment test. The Company performed its annual assessment for goodwill impairment in the fourth quarter of 2014, noting no impairment. There have not been any triggering events through September 30, 2015.

The Company evaluates its long-lived assets with definite lives, such as property and equipment, acquired technology, customer relationships, patent and license rights, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. There have not been any impairment losses of long-lived assets through September 30, 2015.

Investments in Other Entities

The Company holds a portfolio of investments in equity securities that are accounted for under either the equity method or cost method. Investments in entities over which the Company has significant influence but not a controlling interest are accounted for using the equity method, with the Company's share of earnings or losses reported in other income (expense), net.

The Company's cost method investments are included in investments in common stock on the consolidated balance sheets. The Company's equity method investments are included in equity method investments on the consolidated balance sheets.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: market value or exit price of the investment based on either market-quoted prices or future rounds of financing by the investee; length of time that the market value was below its cost basis; financial condition and business prospects of the investee; the Company's intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that we may be aware of related to the investment. The Company does not report the fair value of its equity investments in non-publicly traded companies because it is not practical to do so.

Revenue Recognition

The Company's revenues are generated primarily from various NIH grant awards, and from the sale of customized reagents and the provision of contract development services. The revenue from the NIH grant awards is based upon subcontractor and internal costs incurred that are specifically covered by the grant, and where applicable, a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant.

Revenues from sales are generated from the sale of customized reagents which include industrial standard cytotoxins, linkers, and linker-toxins used for preparing ADCs. Contract development services include providing synthetic expertise to customer's synthesis by delivering proprietary cytotoxins, linkers and linker-toxins and ADC service using industry standard toxin and antibodies provided by customers. Revenue is recognized when, (i) persuasive evidence of an arrangement exists, (ii) the product has been shipped or the services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period.

The Company is obligated to accept from customers the return of products sold that are damaged or do not meet certain specifications. The Company may authorize the return of products sold in accordance with the terms of its sales contracts, and estimates allowances for such amounts at the time of sale. The Company has not experienced any sales returns.

Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates. The up-front and milestone payments to acquire research and development assets that have not reached technological feasibility are immediately expensed as acquired in-process research and development provided that the drugs have not achieved regulatory approval for marketing or have no alternative future use.

Research and Development Costs and Collaborations

All research and development costs are charged to expense as incurred. Such costs primarily consist of lab supplies, contract services, stock-based compensation expense, salaries and related benefits.

Income Taxes

The provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 740-10, Uncertainty in Income Taxes, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has uncertain tax positions. (See Note 11).

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates.

The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized. As of September 30, 2015, the Company maintained a full valuation allowance against its deferred tax assets, with the exception of an amount equal to its deferred tax liabilities, which can be expected to reverse over a definite life.

Stock-based Compensation

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

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options and restricted stock granted to non-employees is re-measured over the vesting period, and the resulting changes in fair value are recognized as expense in the period of the change in proportion to the services rendered to date.

Net Earnings (Loss) per Share

Basic net earnings (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted net earnings (loss) per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options or the exercise of outstanding warrants. The treasury stock method and if-converted method are used to calculate the potential dilutive effect of these common stock equivalents. Potentially dilutive shares are excluded from the computation of diluted net earnings (loss) per share when their effect is anti-dilutive. In periods where a net loss is presented, all potentially dilutive securities are anti-dilutive and are excluded from the computation of diluted net loss per share.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and adjustments for the change in unrealized gains and losses on our investments in available-for-sale marketable securities, net of taxes. The Company displays comprehensive income (loss) and its components in its consolidated statements of comprehensive income (loss).

Segment Information

The Company is engaged primarily in the discovery and development of innovative therapies focused on oncology and the treatment of chronic cancer pain as well as immunology and infectious diseases based on its platform technologies. Accordingly, the Company has determined that it operates in one operating segment.

New Accounting Standards

The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-08, Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity, which amends ASC 205, Presentation of Financial Statements, and ASC 360, Property, Plant and Equipment. This ASU changes the criteria for determining which disposals should be presented as discontinued operation and modifies existing disclosure requirements. The provisions of this update were effective as of January 1, 2015; adoption of the standard had no effect on the Company's financial position, results of operations, or cash flows.

The FASB issued ASU 2014-15, Presentation of Financial Statements — Going Concern, which requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. The provisions of this update are effective as of December 31, 2016, and because the ASU addresses disclosures only, it will not affect the Company's financial position, results of operations, or cash flows.

In June 2014, the FASB issued ASU 2014-12, Compensation-Stock Compensation (Topic 718): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period, or ASU 2014-12. The ASU requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The Company does not expect this standard to have an impact its financial position, results of operations, or cash flows.

In January 2015, the FASB issued ASU No. 2015-01, Income Statement—Extraordinary and Unusual Items (Subtopic 225-20); Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items, which eliminates from GAAP the concept of extraordinary items, stating that the concept causes uncertainty because (1) it is unclear when an item should be considered both unusual and infrequent and (2) users do not find the classification and presentation necessary to identify those events and transactions. This standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, with early adoption permitted provided the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect this standard to have an impact on its financial position, results of operations or cash flows upon adoption.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810)—Amendments to the Consolidation Analysis, or ASU 2015-02. ASU 2015-02 affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. Specifically, the amendments (1) modify the evaluation of whether limited partnerships and similar legal entities are variable interest entities (VIEs) or voting interest entities, (2) eliminate the presumption that a general partner should consolidate a limited partnership, (3) affect the consolidated analysis of reporting entities that are involved with VIEs, and (4) provide a scope exception for certain entities. ASU 2015-02 is effective for interim and annual reporting periods beginning after December 15, 2015. The Company does not expect this standard to have an impact on its financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU 2015-03, Interest—Imputation of Interest (Subtopic 835-30), or ASU 2015-03, which requires the debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the presentation of debt discounts. This guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and

interim periods within those fiscal years. The Company does not expect this standard to affect its financial condition, results of operations, or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The Company is currently evaluating the method of adoption and the potential impact that Topic 606 may have on its financial position and results of operations.

In April 2015, the FASB issued ASU No. 2015-05, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement. Under this standard, if a cloud computing arrangement includes a software license, the software license element of the arrangement should be accounted for consistent with the acquisition of

other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. The new standard will be effective for the Company on January 1, 2016. The adoption of this standard is not expected to have an impact on the Company's financial position or results of operations.

2. Investments

CARgenix

As described more fully in Note 1, the Company and TNK acquired the membership interests in CARgenix. The aggregate purchase price of $6.0 million was recognized as acquired in-process research and development expense in the consolidated statement of operations.

BDL

As described more fully in Note 1, the Company and TNK acquired the membership interests in BDL. The aggregate purchase price of $6.0 million was recognized as acquired in-process research and development expense in the consolidated statement of operations.

As of September 30, 2015 and December 31, 2014, the aggregate carrying amount of the Company's cost-method investments in non-publicly traded companies was $111.5 million and $10.0 million, respectively and as of September 30, 2015 also included an ownership interest in NantCell, Inc., NantBioScience, Inc and Globavir Biosciences, Inc. The Company's cost-method investments are assessed for impairment quarterly. The Company has determined that it is not practicable to estimate the fair value of its cost-method investments on a regular basis and does not reassess the fair value of cost-method investments if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investments. No impairment losses were recorded during the three and nine months ended September 30, 2015 and 2014.

3. Equity Method Investments

NANTibody

As described in Note 1, the Company and NantCell established a new joint venture called NANTibody, as a stand-alone biotechnology company. NANTibody will focus on accelerating the development of multiple immuno-oncology monoclonal antibodies (mAbs) for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-check point antibodies as well as antibody drug conjugates (ADCs) and bispecific antibodies.

NANTibody had no significant operations and incurred minimal general and administrative expenses during the three and nine months ended September 30, 2015.

NantStem

As described in Note 1, the Company and NantBioScience established a new joint venture called NantStem, as a stand-alone biotechnology company. NantStem will focus on the development of small molecule compounds against targets which may address important drivers of cancer growth including cancer stem cells. The Company agreed to contribute specified small molecule programs (lead inhibitors of the proto-oncogenes c-Myc, and the master

metabolism regulator HIF-1 alpha, and an inducer of the tumor suppressor cytokine TRAIL) to NantStem. The value of the items contributed by the Company were insignificant.

NantStem had no significant operations and incurred minimal general and administrative expenses during the three and nine months ended September 30, 2015.

4. Marketable Securities

Marketable securities consisted of the following as of September 30, 2015 (in thousands):

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term available-for-sale securities:				
NantKwest common shares	$10,000	$ 54,386	$ —	$64,386

On July 27, 2015, NantKwest, Inc. completed its initial public offering ("IPO"). Prior to the IPO the Company's investment in NantKwest was accounted for using the cost method and the total investment of $10.0 million was classified as part of investments in common stock on the Company's consolidated balance sheets. The common shares are subject to restrictions in a lock-up agreement through December 27, 2015 as well as limitations under Rule 144 of the Securities Act of 1933. As these are short term restrictions, the Company did not apply a marketability discount. The Company recorded an unrealized gain of $54.4 million, representing the difference between the $10.0 million cost basis and the estimated fair value net of tax as of September 30, 2015, as accumulated other comprehensive income in the stockholder's equity section of the Company's consolidated balance sheet and as a change in unrealized gains and losses on marketable securities in the Company's consolidated statements of comprehensive income (loss). The Company's investment in NantKwest, Inc. will be revalued on each balance sheet date. The fair value of the Company's holdings in NantKwest at September 30, 1015 is a Level 1 measurement.

5. Sale of IgDraSol

On July 8, 2015, the Company consummated the previously announced sale to NantPharma of its equity interests in IgDraSol, Inc., its wholly-owned subsidiary and the holder of the rights to Cynviloq, a polymeric micelle based Cremophor free paclitaxel injectable finished formulation. Pursuant to the Agreement, NantPharma paid the Company an upfront payment of $90.05 million, of which $60 million was paid to NANTibody and NantStem by NantPharma on the Company's behalf to fund the Company's joint ventures. In addition, the Company will be entitled to receive up to $620 million in regulatory milestone payments and up to $600 million in sales milestone payments should certain events occur. The Company will also receive specified additional per unit payments in excess of cost of supply from total unit sales. In addition, during the first three years after closing, the Company has the option to co-develop and/or co-market Cynviloq on terms to be negotiated.

Upon the closing of the sale agreement in July 2015, a specified development milestone in the Agreement and Plan of Merger between the Company and IgDraSol, Inc. dated September 9, 2013, was satisfied and the Company issued 1,306,272 million shares to former IgDraSol stockholders. At the time of the IgDraSol acquisition, the Company estimated that the probability of achieving these development milestones was remote and therefore the Company did not assign any value to these milestones.

The Company recorded the following amounts in the third quarter of 2015, resulting in a net gain of $69.3 million on the sale of the IgDraSol assets calculated as the difference between the non-contingent consideration and the net carrying amount of the assets and liabilities assumed or extinguished. The following sets forth the calculation of the gain on sale as of the closing (in thousands):

	Amount
Non-contingent cash consideration received	$90,050
Net intangible assets sold	(17,193)
Allocated goodwill	(3,415)
Extinguished employee liabilities and estimated transaction costs	(168)
Gain on sale of IgDraSol, net	$69,274

The net gain on the sale of the IgDraSol assets may be adjusted in future periods by contingent consideration based upon the achievement of pre-determined regulatory and revenue milestones.

In determining the gain on sale, $3.4 million of goodwill was allocated on a relative fair value basis comparing the fair value of the IgDraSol business to the fair value of the Company.

6. Goodwill and Intangible Assets

As of September 30, 2015 and December 31, 2014, the Company had goodwill of $20,626 and $24,041, respectively. The Company performed a qualitative test for goodwill impairment as of December 31, 2014. Based upon the results of the qualitative testing the Company concluded that it is more-likely-than-not that the fair values of the Company's goodwill was in excess of its carrying value and therefore performing the first step of the two-step impairment test was unnecessary. No goodwill impairment was recognized for the three and nine months ended September 30, 2015 and 2014.

The following is a summary of changes in the Company's recorded goodwill during the nine months ended September 30, 2015 (in thousands):

	Amount
Balance at December 31, 2014	$24,041
Relative fair value allocation of goodwill attributable to IgDraSol upon sale to NantPharma (see Note 5)	(3,415)
Balance as September 30, 2015	$20,626

The Company's intangible assets, excluding goodwill, include patent rights, core technologies and customer relationships. Amortization for the intangible assets that have finite useful lives is generally recorded on a straight-line basis over their useful lives. A summary of the Company's identifiable intangible assets is as follows:

	September 30, 2015		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	$1,320	$ 472	$ 848
Acquired technology	3,410	313	3,097
Patent rights	90	12	78
Total intangible assets	$4,820	$ 797	$ 4,023

	December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Customer relationships	$1,320	$ 272	$ 1,048
Acquired technology	3,410	182	3,228
Patent rights	90	9	81
Total intangible assets	$4,820	$ 463	$ 4,357

As of September 30, 2015, the remaining amortization period for identifiable intangible assets is 5 to 19 years.

Patent rights are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately nineteen years from the date of transfer of the rights to the Company in April 2013. Amortization expense for both the three and nine months ended September 30, 2015 and 2014 was $1 and $4, respectively, which has been included in intangibles amortization.

Acquired technology is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately nineteen years from the date of acquisition of the technology in December 2013. Amortization expense for both the three and nine months ended September 30, 2015 and 2014 was $50 and $150, respectively, which has been included in intangibles amortization.

Customer relationships are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately five years from the date of acquisition in December 2013. Amortization expense for both the three and nine months ended September 30, 2015 and 2014 was $66 and $198, respectively, which has been included in intangibles amortization.

Estimated future amortization expense related to intangible assets at September 30, 2015 is as follows:

Years Ending December 31,	Amount
2015 (remaining three months)	$ 110
2016	445

2017	445
2018	436
2019	181
Thereafter	2,406
Total	$ 4,023

7. Significant Agreements and Contracts

License Agreement with The Scripps Research Institute

In January 2010, the Company entered into a license agreement, or the TSRI License, with The Scripps Research Institute, or TSRI. Under the TSRI License, TSRI granted the Company an exclusive, worldwide license to certain TSRI patent rights and materials based on quorum sensing for the prevention and treatment of Staphylococcus aureus (“Staph”) infections, including Methicillin-resistant Staph. In consideration for the license, the Company: (i) issued TSRI a warrant for the purchase of common stock, (ii) agreed to pay TSRI a certain annual royalty commencing in the first year after certain patent filing milestones are achieved, (iii) agreed to pay a royalty on any sales of licensed products by the Company or its affiliates and a royalty for any revenues generated

by the Company through its sublicense of patent rights and materials licensed from TSRI under the TSRI License. The TSRI License requires the Company to indemnify TSRI for certain breaches of the agreement and other matters customary for license agreements. The parties may terminate the TSRI License at any time by mutual agreement. In addition, the Company may terminate the TSRI License by giving 60 days' notice to TSRI and TSRI may terminate the TSRI License immediately in the event of certain breaches of the agreement by the Company or upon the Company's failure to undertake certain activities in furtherance of commercial development goals. Unless terminated earlier by either or both parties, the term of the TSRI License will continue until the final expiration of all claims covered by the patent rights licensed under the agreement. The warrant was exercised in February 2015. For the three months ended September 30, 2015 and 2014, the Company recorded $48 and $41 in patent prosecution and maintenance costs associated with the TSRI License, respectively. For the nine months ended September 30, 2015 and 2014, the Company recorded $94 and $97 in patent prosecution and maintenance costs associated with the TSRI License, respectively. All such costs have been included in general and administrative expenses.

License Agreement with Mabtech Limited

In August 2015, the Company entered into an exclusive licensing agreement to develop and commercialize multiple prespecified biosimilar and biobetter antibodies from Mabtech Limited. Under the terms of the agreement, the Company will develop and market these four monoclonal antibodies (mAbs) for the North American, European and Japanese market. The Company made an initial license payment of $10.0 million which was recognized as acquired in-process research and development expense in the consolidated statements of operations. The agreement includes additional milestone payments totaling up to $190.0 million payable over the next five years.

License Agreement with NantCell

In April 2015, the Company and NantCell entered into a license agreement. Under the terms of the agreement the Company granted an exclusive license to NantCell covering patent rights, know-how, and materials related to certain antibodies, anti-body drug conjugates (ADC) and two CAR-TNK products. NantCell agreed to pay a royalty not to exceed five percent (5%) to the Company on any net sales of products (as defined) from the assets licensed by the Company to NantCell. In addition to the future royalties payable under this agreement, NantCell paid an upfront payment of $10 million to the Company and issued 10 million shares of NantCell common stock to the Company valued at $100 million based on a recent equity sale of NantCell common stock to a third party. The Company will recognize the upfront payment and the value of the equity interest received over the expected license period of approximately ten years on a straight line basis. The Company's ownership interest in NantCell does not provide the Company with control or the ability to exercise significant influence, therefore the $100 million investment will be carried at cost in the consolidated balance sheets and evaluated for other-than-temporary impairment on a quarterly basis.

NIH Grants

In June 2012, the NIAID awarded the Company a third Advanced Technology STTR grant to support the Company's program to generate and develop novel human antibody therapeutics to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant II award. The project period for the Phase I grant covers a two-year period which commenced in June 2012, with a total grant award of $600. During the three months ended September 30, 2015 and 2014, the Company recorded no revenue, respectively, associated with the Staph Grant II award. During the nine months ended September 30, 2015 and 2014, the Company recorded $0 and $150 of revenue, respectively, associated with the Staph Grant II award.

In June 2014, the NIAID awarded the Company a Phase II STTR grant to support the advanced preclinical development of human bispecific antibody therapeutics to prevent and treat Staphylococcus aureus (S. aureus or Staph) infections, including methicillin-resistant S. aureus (MRSA), or the Staph Grant III award. The project period for this Phase II grant covers a two-year period which commenced in June 2014, with total funds available of

approximately $1 million per year for up to 2 years. During the three months ended September 30, 2015 and 2014, the Company recorded $243 and $115 of revenue, respectively, associated with the Staph Grant III award. During the nine months ended September 30, 2015 and 2014, the Company recorded $660 and $147 of revenue, respectively, associated with the Staph Grant III award.

In June 2014, the NIAID awarded the Company a Phase I STTR grant entitled “Anti-Pseudomonas Immunotherapy and Targeted Drug Delivery”. This grant will support the preclinical development of novel anti-Pseudomonas aeruginosa mAb immunotherapy or an antibody-mediated targeted antibiotic delivery vehicle. Each modality may be an effective and safe stand-alone therapy and/or a component of a “cocktail” therapeutic option for prevention and treatment of P. aeruginosa infections. The project period for this Phase I grant covers a two-year period which commenced in July 2014, with total funds available of approximately $300 per year for up to 2 years. During the three months ended September 30, 2015 and 2014, the Company recorded $73 and $11 of revenue, respectively, associated with the Phase I STTR grant award. During the nine months ended September 30, 2015 and 2014, the Company recorded $167 and $11 of revenue, respectively, associated with the Phase I STTR grant award.

In July 2014, the National Cancer Institute (NCI), a division of the NIH, awarded the Company a Phase I STTR grant, entitled “Targeting of Myc-Max Dimerization for the Treatment of Cancer”. This grant will support the preclinical development of the Myc inhibitor, which interferes with the protein-protein interaction (PPI) between Myc and its obligatory dimerization partner, Max, preventing sequence-specific binding to DNA and subsequent initiation of oncogenic transformation. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the three months ended September 30, 2015 and 2014, the Company recorded $9 and $19 of revenue, respectively, associated with the Phase I Myc grant award. During the nine months ended September 30, 2015 and 2014, the Company recorded $139 and $19 of revenue, respectively, associated with the Phase I Myc grant award.

In August 2014, the National Heart, Lung, and Blood Institute (NHBLI), a division of the NIH awarded the Company a Phase I Small Business Technology Transfer (SBIR) grant entitled “Human Anti-WISP-1 Antibodies for Treatment of Idiopathic Pulmonary Fibrosis”. This grant will advance the Company’s immunotherapy targeting WNT-1 Inducible Signaling Protein-1(WISP1) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). WISP1 is a protein that has been shown to be upregulated in IPF, linked to key growth factors, cellular proliferation, hyperplasia and is correlated with late stage cancers. IPF is a fatal disease, which results in progressive loss of lung function due to fibrosis of the lungs. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the three months ended September 30, 2015 and 2014, the Company recorded $31 and $2 of revenue, respectively, associated with the Phase I WISP1 grant award. During the nine months ended September 30, 2015 and 2014, the Company recorded $61 and $2 of revenue, respectively, associated with the Phase I WISP1 grant award.

8. Loan and Security Agreement

In September 2013, the Company entered into a $5.0 million loan and security agreement with two banks pursuant to which: (i) the lenders provided the Company a term loan which was funded at closing, (ii) the Company repaid its then outstanding equipment loan balance of $762, and (iii) the lenders received a warrant to purchase an aggregate 31,250 shares of the Company’s common stock at an exercise price of $8.00 per share exercisable for seven years from the date of issuance. The value of the warrants, totaling $215, was recorded as debt discount and additional paid-in capital.

In March 2014, the Company entered into an amended and restated loan and security agreement, increasing the September 2013 facility to $12.5 million from $5.0 million, with the same two banks. Such loan was funded at closing and is secured by a lien covering substantially all of the Company’s assets, excluding intellectual property, which is subject to a negative pledge. In October 2014, the Company entered into a second amendment to its amended and restated loan and security agreement to extend the interest only payments on the outstanding amount of the loan from October 1, 2014 to May 1, 2015, after which equal monthly payments of principal and interest are due until the loan maturity date of September 30, 2017. The amended and restated loan: (i) interest rate is 7.95% per annum, and (ii) provided the Lenders additional warrants to purchase an aggregate of 34,642 shares of the Company’s common stock at an exercise price of $12.99 per share, exercisable for seven years from the date of issuance. The value of the warrants, totaling $321, was recorded as debt discount and additional paid-in capital.

At the Company’s option, it may prepay all of the outstanding principal balance, subject to certain pre-payment fees ranging from 1% to 3% of the prepayment amount. In the event of a final payment of the loans under the loan agreement, either in the event of repayment of the loan at maturity or upon any prepayment, the Company is obligated to pay the amortized portion of the final fee of $781.

The Company is also subject to certain affirmative and negative covenants under the loan agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise

dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; and make or permit any payment on specified subordinated debt. In addition, under the loan agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts.

Long-term debt and unamortized discount balances are as follows (in thousands):

Face value of amended and restated loan	$10,585
Fair value of all warrants	(536)
Accretion of debt discount	319
Balance at September 30, 2015	$10,368

Future minimum payments under the amended and restated loan and security agreement are as follows:

Year Ending December 31,	
2015	$1,313
2016	5,530
2017	4,608
Total future minimum payments	11,451
Unamortized interest	(866)
Debt discount	(217)
Total minimum payment	10,368
Current portion	(4,722)
Long-term debt	$5,646

9. Stock Incentive Plans

2009 Non-Employee Director Grants

In September 2009, prior to the adoption of the 2009 Stock Incentive Plan, the Company's Board of Directors approved the reservation and issuance of 8,000 nonstatutory stock options to the Company's non-employee directors. The outstanding options vested on the one year anniversary of the vesting commencement date in October 2010, and are exercisable for up to 10 years from the grant date. No further shares may be granted under this plan and, as of September 30, 2015, 3,200 options were outstanding.

2009 Stock Incentive Plan

In October 2009, the Company's stockholders approved the 2009 Stock Incentive Plan. In June 2014, the Company's stockholders approved, among other items, the amendment and restatement of the 2009 Stock Incentive Plan, or the Stock Plan, to increase the number of common shares authorized to be issued pursuant to the Stock Plan to 3,760,000. Such shares of the Company's common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. The Stock Plan provides for the grant of incentive stock options, non-incentive stock options, stock appreciation rights, restricted stock awards, unrestricted stock awards, restricted stock unit awards and performance awards to eligible recipients. Recipients of stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Stock Plan is ten years. Employee option grants will generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years. The vesting schedules for grants to non-employee directors and consultants will be determined by the Company's Compensation Committee.

The following table summarizes stock option activity as of September 30, 2015 and the changes for the period then ended:

	Options Outstanding	Weighted-Average	Aggregate Intrinsic Value

		Exercise Price	
Outstanding at December 31, 2014	2,231,800	$ 6.34	$ 8,323
Options Granted	1,328,600	$ 12.74	
Options Canceled	(217,762)	$ 7.02	
Options Exercised	(272,338)	$ 6.16	
Outstanding at September 30, 2015	3,070,300	$ 8.84	$ (1,367)

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of employee stock options was estimated at the grant date using the following assumptions:

	Nine Months Ended September 30,	
	2015	2014
Weighted-average grant date fair value	$11.56	$8.05
Dividend yield	—	—
Volatility	75 %	78 %
Risk-free interest rate	1.65 %	1.95 %
Expected life of options	6.1 years	6.1 years

The assumed dividend yield was based on the Company’s expectation of not paying dividends in the foreseeable future. Due to the Company’s limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable

companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options.

The total employee stock-based compensation recorded as operating expenses was $2,373 and $490 for the three months ended September 30, 2015 and 2014, respectively, and $4,156 and $2,619 for the nine months ended September 30, 2015 and 2014, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2015 was $8,509 and the weighted average period over which these grants are expected to vest is 2.6 years.

The Company records equity instruments issued to non-employees as expense at their fair value over the related service period as determined in accordance with the authoritative guidance and periodically revalues the equity instruments as they vest. Stock-based compensation expense related to non-employee consultants recorded as operating expenses was $280 and $136 for the three months ended September 30, 2015 and 2014, respectively, and $1,327 and $540 for the nine months ended September 30, 2015 and 2014, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at September 30, 2015:

Common stock warrants outstanding under the underwriters agreement	182,600
Common stock warrants outstanding under the loan and security agreement	65,892
Common stock warrants outstanding under the Cambridge securities agreement	1,724,138
Common stock options outstanding under the EIP	3,200
Authorized for future grant or issuance under the Stock Plan	330,862
Issuable under assignment agreement based upon achievement of certain milestones	80,000
	2,386,692

The Company had outstanding common share equivalents of 5,046,130 and 2,091,826 at September 30, 2015 and 2014, respectively.

10. Investment in Variable Interest Entity

The Company's consolidated financial statements include the financial results of LA Cell, Inc. (LA Cell), a consolidated subsidiary of the Company and a variable interest entity in which the Company is the primary beneficiary.

In September 2015, LA Cell exclusively licensed certain technology from City of Hope. The technology includes cell-penetrating antibody therapies that enables modified monoclonal antibodies (mAbs) to penetrate into cells and target disease-causing molecules. Utilizing mAbs derived from the Company's antibody portfolio, LA Cell is focused on developing therapies against important oncology targets, including but not limited to c-MYC, mutated KRAS, STAT3, and FoxP3. Pursuant to the license agreement, LA Cell made a $2.0 million upfront payment to City of Hope and will pay an additional initial payment of $3.0 million to City of Hope by March 25, 2016, as well as license maintenance fees over the next six years. The license agreement also provides for development and sales milestone

payments and royalties based on net sales, as defined in the license agreement.

Upon the formation of LA Cell, the Company held all of the outstanding stock of LA Cell. As of September 30, 2015, the Company held an aggregate of approximately a 43% ownership of outstanding shares but which include a majority of the voting rights.

For the three and nine months ended September 30, 2015, LA Cell recognized $2.0 million in acquired in-process research and development expense in the Company’s consolidated statements of operations and incurred minimal general and administrative expenses.

11. Income Taxes

The Company maintains deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, research credits and temporary differences. In assessing the Company's ability to

realize deferred tax assets, management considers, on a periodic basis, whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. As such, management has determined that it is appropriate to maintain a full valuation allowance against the Company's U.S. federal and state deferred tax assets, with the exception of an amount equal to its deferred tax liabilities, which can be expected to reverse over a definite life.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2007 and later are subject to examination by the U.S. and state tax authorities due to the existence of the NOL carryforwards.

As of the September 30, 2015, the Company had approximately $800 of unrecognized tax benefits that, if recognized, would impact the effective income tax rate for continuing operations, subject to possible offset by an increase in the deferred tax asset valuation allowance. As of September 30, 2014, there were no unrecognized tax benefits.

Income taxes payable as of September 30, 2015, are included in accrued expenses in the Company’s consolidated balance sheet.

The Company recognizes interest and penalties related to unrecognized tax benefits in its provision for income taxes. For the nine months ended September 30, 2014 and September 30, 2015, expense was recorded related to interest and penalties. For the nine months ended September 30, 2014 and September 30, 2015, there was no material benefit recorded related to interest and penalties. The Company believes that no significant amount of the liabilities for uncertain tax positions will expire within twelve months of September 30, 2015.

A reconciliation of the income tax provision from operations computed by applying the statutory federal income tax rate of 35% to income (loss) from operations before income taxes to the income tax provision for the nine months ended September 30, 2015 was as follows (in thousands):

	September 30, 2015
Income tax benefit at federal statutory rate	$ (9,828)
State, net of federal tax benefit	(957)
Non-deductible expense and other	4,576
Gain on sale of IgDraSol	6,055
Impact of indefinite lived deferred tax liabilities	36,661
Income tax credits	(4,641)
Increase in valuation allowance	3,262
Income tax provision	$ 35,128

12. Related Party Agreements

During the three and nine months ended September 30, 2015, the Company purchased products totaling $76 and $491, respectively, from Levena Biopharma Co., LTD (Levena), a Chinese Corporation. The Company’s Senior Vice President and Head of Antibody Drug Conjugates is also one of the owners of Levena.

In December 2014, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with an affiliated entity of Dr. Patrick Soon-Shiong (the “Investor”) pursuant to which the Company agreed to issue and sell to the Investor an aggregate of approximately 7.2 million shares of the Company’s common stock at a price of $5.80 per share for an aggregate purchase price of $41,691. In connection with the Purchase Agreement, the Investor received a warrant to purchase approximately 1.7 million shares of the Company’s Common Stock. The warrant is exercisable for a period of three years from the date of issuance at an initial exercise price of $5.80 per share.

In December 2014, the Company entered into a joint development and license agreement with Conkwest Inc., which has changed its name to NantKwest, and of which Dr. Patrick Soon-Shiong is a majority owner. In addition, the Company purchased approximately 5.6 million shares of NantKwest common stock for $10 million.

As described more fully in Notes 1 and 3, during the nine months ended September 30, 2015, the Company entered into a joint venture called Immunotherapy NANTibody, LLC, with NantCell, a wholly-owned subsidiary of NantWorks, a private company owned by Dr. Patrick Soon-Shiong. In July 2015, the Company contributed its portion of the initial joint funding of $40 million to the Immunotherapy NANTibody joint venture. The Company and NantCell have also entered into a license agreement pursuant to which the Company received a $10 million upfront license payment and $100 million of vested NantCell common stock.

As described more fully in Notes 1 and 3, the Company entered into a joint venture called NantCancerStemCell, LLC, or NantStem, with NantBioScience, a wholly-owned subsidiary of NantWorks. In connection with negotiated changes to the structure of

NantStem the Company issued a call option on shares of NantKwest that it owned to Cambridge Equities, LP (Cambridge), a related party to the Company and to NantBioScience. The call option to Cambridge is on up to 2.0 million shares of NantKwest common stock held by the Company (the Option Agreement). The Company currently holds approximately 5.6 million shares of common stock of NantKwest, which is classified as available-for-sale in the consolidated financial statements. The Option Agreement gives Cambridge the right to purchase up to 2.0 million shares at a price of $15.295 from time to time in the first quarter of 2016. There is no option premium associated with this Option Agreement. The Option Agreement is a derivative as defined in ASC 815 and will be marked to fair value every reporting period the Option Agreement is in effect, with changes in fair value recognized in current earnings. In April 2015, the Company purchased 1.0 million shares of NantBioScience common stock for $10 million.

In May 2015, the Company entered into a stock sale and purchase agreement with NantPharma, a private company owned by NantWorks pursuant to which the Company sold its equity interests in IgDraSol, its wholly-owned subsidiary and holder of the rights to Cynviloq for an upfront payment of $90.05 million and potential regulatory and sales milestones of up to $1.2 billion. See Note 5.

13. Subsequent Events

On October 13, 2015, the Company wrote a call option to Cambridge Equities, LP (Cambridge), a related party, on up to 2.0 million shares of NantKwest, Inc (NantKwest) common stock held by the Company (the Option Agreement). The Company currently holds approximately 5.6 million shares of common stock of NantKwest, par value $.0001 per share, which is classified as available-for-sale in its consolidated financial statements. The Option Agreement gives Cambridge the right to purchase up to 2.0 million shares at a price of $15.295 from time to time in the first quarter of 2016. There is no option premium associated with this Option Agreement. The Option Agreement is a derivative as defined in ASC 815 and will be marked to fair value every reporting period the Option Agreement is in effect, with changes in fair value recognized in current earnings.

In August 2015, the Company and TNK entered into a binding term sheet to exclusively license the NanoVelcro Circulating Tumor Cell profiling assay (the “Technology”) from Cytolumina Technologies Corp. (“CTC”) and Fetolumina Technologies Corp. (“FTC”). Upon execution of definitive license agreements, CTC and FTC each agreed to grant to TNK an exclusive and perpetual license to the Technology to research, develop, use, offer for sale, sell, have sold, distribute, import, and export the Technology and any products developed from or includes the Technology (the “Product”) for all uses or applications for cell based therapies, including but not limited to CAR-T and CAR.TNK immunotherapies (the “TNK Field”). Additionally, CTC and FTC each agreed to grant to the Company an exclusive and perpetual license to the Technology to research, develop, use, offer for sale, sell, have sold, distribute, import and export the Technology and any Products that incorporate a Company proprietary antibody for uses or applications. As of September 30, 2015 this transaction had not closed.

Upon execution of final definitive license agreements, TNK shall acquire 4.166% of the capital stock of each of CTC and FTC for an aggregate purchase price of $5.0 million. In addition, the definitive license agreements shall provide that TNK, on the one hand, and CTC and FTC, on the other hand, shall share the profits from the net sales of TNK for any Product in the TNK Field on a 50/50 basis. The Company, on the one hand, and CTC and FTC, on the other hand, shall share the profits from net sales of the Company for any Product that incorporates a Company proprietary antibody outside the TNK Field on a 50/50 basis. CTC and FTC shall pay the Company 10% of the net profit of CTC and FTC, respectively, for sales of any Product that incorporates a Company proprietary antibody outside the TNK Field.

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

This Quarterly Report on Form 10-Q contains "forward-looking statements" about our expectations, beliefs or intentions regarding our potential product offerings, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made and are often identified by the use of words such as "assumes," "plans," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," or "will," and similar expressions or variations forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described under the caption "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q and in our other filings with the Securities and Exchange Commission, or the SEC. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Overview

We are a biopharmaceutical company engaged in the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs in the U.S. as well as international markets. Our primary therapeutic focus is oncology, including the treatment of chronic cancer pain, but we are also developing therapeutic products for other indications, including immunology and infectious diseases. We currently have multiple clinical development programs underway: CAR-T programs for solid tumors, resiniferatoxin, or RTX, a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for intractable pain in end-stage disease and our clinical development program for our biosimilar/biobetter antibodies that we licensed from Mabtech Limited, a holding company for antibody development and manufacturing companies in China.

Our pipeline also includes preclinical fully human therapeutic monoclonal antibodies (mAbs), including our fully human anti-PD-L1 and anti-PD-1 checkpoint inhibitors derived from our proprietary G-MAB® library platform, antibody drug conjugates (ADCs), bispecific antibodies (BsAbs), as well as Chimeric Antigen Receptor-T cell (CAR-T) and Chimeric Antigen Receptor Tumor-attacking Neukoplast® (CAR.TNK™, pronounced "CARTANK") for adoptive cellular immunotherapies (ACI). Our objective is to develop our antibody drug products and adoptive cellular immunotherapies as: (i) First in Class (FIC), and/or (ii) Best in Class (BIC), which may offer greater efficacy and/or fewer adverse events or side effects as compared to existing drugs, as well as fully human therapeutic antibodies derived from our proprietary G-MAB® library platform and antibody drug conjugates, or ADCs.

Through September 30, 2015, we identified and further developed a number of potential product candidates across various therapeutic areas, and intend to select several lead product candidates to further advance into preclinical development activities in 2016. It is too early to assess which of these candidates, if any, will merit further evaluation in clinical trials. Our libraries were designed to facilitate the rapid identification and isolation of highly specific, antibody therapeutic product candidates that are fully-human and that bind to disease targets appropriate for antibody therapy. We built our initial antibody expression and production capabilities to enable us to make sufficient product material to conduct preclinical safety and efficacy testing in animal models.

Although we intend to retain ownership and control of product candidates by advancing their development, we regularly also consider, (i) partnerships with pharmaceutical or biopharmaceutical companies and (ii) sale of our products in each case, in order to balance the risks and costs associated with drug discovery, development and commercialization with efforts to maximize our stockholders' returns. Our partnering objectives include generating revenue through license fees, milestone-related development fees and royalties as well as profit shares or joint ventures to generate potential returns from our product candidates.

Recent Developments

In June 2015, the National Institutes of Health, or NIH announced that the Clinical Center suspended operations of its Pharmaceutical Development Section after FDA inspections that occurred in May 2015. An FDA inspection report issued on May 29, 2015 noted “deficiencies in the physical facility, including flaws in the air handling system, and operational failures including inadequate quality control, insufficient employee training, and lack of compliance with standard operating procedures”. As a result, 46 clinical programs, including the resiniferatoxin (RTX) study in patients with severe pain in advanced cancer, were placed on clinical hold by the FDA. NIH has developed an interim corrective action/preventative action plan which has not yet been approved by the FDA. The Company plans to continue with its already planned corporate IND for RTX.

In August 2015, we along with TNK Therapeutics, Inc. ("TNK"), our subsidiary entered into a Membership Interest Purchase Agreement (the "Membership Interest Purchase Agreement") with CARgenix Holdings LLC ("CARgenix") and the members of CARgenix (the "Members") pursuant to which the Members sold all of their membership interests in CARgenix to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A common stock, subject to adjustment in certain circumstances, to be issued to the Members upon a financing resulting in gross proceeds (individually or in the aggregate) to TNK of at least $50.0 million (a "Qualified Financing"). In the event a Qualified Financing does not occur by March 15, 2016 or TNK does not complete an initial public offering of shares of its capital stock by March 31, 2016, in lieu of receiving shares of TNK pursuant to the acquisition, the Members shall receive an aggregate of 309,917 shares of our common stock, subject to adjustment in certain circumstances. The Membership Interest Purchase Agreement further provides that 20% of the shares of TNK or ours, as applicable, issuable to the Members shall be held in escrow to secure certain post-closing adjustment and indemnification rights of TNK for a period of 12 months following the closing of the transaction. The aggregate purchase price of $6.0 million was recognized as acquired in-process research and development expense in the consolidated statement of operations.

In August 2015, we along with TNK entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") with BDL Products, Inc. ("BDL") and the stockholders of BDL ("Stockholders") pursuant to which the Stockholders sold all of their shares of capital stock in BDL to TNK for: (1) a cash payment of $100.00, and (2) $6.0 million in shares of TNK Class A common stock, subject to adjustment in certain circumstances, to be issued to the Stockholders upon a Qualified Financing. In the event a Qualified Financing does not occur by March 15, 2016 or TNK does not complete an initial public offering of shares of its capital stock by March 31, 2016, in lieu of receiving shares of TNK pursuant to the acquisition, the Stockholders shall receive an aggregate of 309,917 shares of our common stock, subject to adjustment in certain circumstances. The Stock Purchase Agreement further provides that 20% of the shares of TNK or ours, as applicable, issuable to the Stockholders shall be held in escrow to secure certain post-closing adjustment and indemnification rights of TNK for a period of 12 months following the closing of the transaction. The aggregate purchase price of $6.0 million was recognized as acquired in-process research and development expense in the consolidated statement of operations.

In August 2015, we entered into an exclusive licensing agreement to develop and commercialize multiple prespecified biosimilar or biobetter antibodies from Mabtech Limited. Under the terms of the agreement, we will develop and market these four monoclonal antibodies (mAbs) for the North American, European and Japanese market. We made an initial license payment of $10.0 million which was recognized as acquired in-process research and development expense in the consolidated statements of operations. The agreement includes additional payments totaling up to $190.0 million payable over the next five years.

In July 2015, we and NantBioScience established a new joint venture called NantCancerStemCell, LLC, or NantStem, as a stand-alone biotechnology company with $100 million initial joint funding. As initially organized, NantBioScience was obligated to make a $60 million cash contribution to NantStem for a 60% equity interest in NantStem, and we were obligated to make a $40 million cash contribution to NantStem for a 40% equity interest in NantStem. Fifty percent of these contributions were funded in July 2015 and the remaining amounts were be made by no later than September 30, 2015. We had NantPharma contribute our portion of the initial joint funding of $20 million to NantStem from the proceeds of the sale of IgDraSol. Pursuant to a Side Letter dated October 13, 2015, the NantStem joint venture agreement was amended to relieve us of the obligation to contribute the second $20 million payment, and our ownership interest in NantStem was reduced to 20%. NantBioScience's funding obligations were unchanged. The Side Letter was negotiated at the same time we issued a call option on shares of NantKwest that we owned to Cambridge Equities, LP, a related party to us and to NantBioScience.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements which are prepared in accordance with GAAP. The preparation of these financial

statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to income taxes and stock-based compensation. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

During the quarter ended September 30, 2015, there were no significant changes to the items that we disclosed as our critical accounting policies and estimates in Note 2 to our consolidated financial statements for the year ended December 31, 2014 contained in our 2014 Form 10-K, as filed with the SEC.

Results of Operations

The following describes certain line items set forth in our consolidated statements of operations.

Comparison of the Three Months Ended September 30, 2015 and 2014

(figures in 000's unless otherwise specified)

Revenues. Revenues were $1,103 for the three months ended September 30, 2015, as compared to $1,276 for the three months ended September 30, 2014. The net decrease of $173 is primarily due to lower sales and service revenues generated from the sale of customized reagents and providing contract development services partially offset by more active grants and an increase in activities under our active grants for the three months ended September 30, 2015 compared to the corresponding period of 2014.

In June 2014, the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, or NIH awarded us a Phase II STTR grant to support the advanced preclinical development of human bispecific antibody therapeutics to prevent and treat Staphylococcus aureus (S. aureus or Staph) infections, including methicillin-resistant S. aureus (MRSA), or the Staph Grant III award. The project period for this Phase II grant covers a two-year period which commenced in June 2014, with total funds available of approximately $1 million per year for up to 2 years. During the three months ended September 30, 2015 and 2014, we recorded $243 and $115 of revenue, respectively, associated with the Staph Grant III award.

In June 2014, we were awarded a Phase I STTR grant entitled "Anti-Pseudomonas Immunotherapy and Targeted Drug Delivery" from the NIAID. This grant will support the preclinical development of novel anti-Pseudomonas aeruginosa mAb immunotherapy or an antibody-mediated targeted antibiotic delivery vehicle. Each modality may be an effective and safe stand-alone therapy and/or a component of a "cocktail" therapeutic option for prevention and treatment of P. aeruginosa infections. The project period for this Phase I grant covers a two-year period which commenced in July 2014, with total funds available of approximately $300 per year for up to 2 years. During the three months ended September 30, 2015 and 2014, we recorded $73 and $11 of revenue, respectively, associated with the Phase I STTR grant award.

In July 2014, we were awarded a Phase I STTR grant from the National Cancer Institute (NCI), a division of the NIH, entitled "Targeting of Myc-Max Dimerization for the Treatment of Cancer". This grant will support the preclinical development of the Myc inhibitor, which interferes with the protein-protein interaction (PPI) between Myc and its obligatory dimerization partner, Max, preventing sequence-specific binding to DNA and subsequent initiation of oncogenic transformation. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the three months ended September 30, 2015 and 2014, we recorded $10 and $19 of revenue, respectively associated with the Phase I Myc grant award.

In August 2014, we were awarded a Phase I Small Business Technology Transfer (SBIR) grant from the National Heart, Lung, and Blood Institute (NHBLI), a division of the NIH, entitled "Human Anti-WISP-1 Antibodies for Treatment of Idiopathic Pulmonary Fibrosis". This grant will advance the Company's immunotherapy targeting WNT-1 Inducible Signaling Protein-1(WISP1) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). WISP1 is a protein that has been shown to be upregulated in IPF, linked to key growth factors, cellular proliferation, hyperplasia and is correlated with late stage cancers. IPF is a fatal disease, which results in progressive loss of lung function due to fibrosis of the lungs. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the three months ended September 30, 2015 and 2014, we recorded $31 and $2 of revenue, respectively, associated with the Phase I WISP1 grant award.

Revenues from a human immune-oncology anti PD-L1 license agreement for the three months ended September 30, 2015 and 2014, were $12 and $0, respectively. We had no other revenue during the three months ended September 30, 2015 and 2014 as we have not yet developed any product candidates for commercialization or earned any licensing or royalty payments.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the unpredictability of the demand for products and services offered as well as the timing and amount of grant awards, research and development reimbursements and other payments received under any strategic collaborations, if any.

Cost of revenues. Cost of revenues for the three months ended September 30, 2015 and 2014 were $604 and $527, respectively, and relate to the sale of customized reagents and providing contract development services. The costs generally include employee-related expenses including salary and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2015 and 2014 were $7,244 and $5,440, respectively. Research and development expenses include the costs to advance our RTX program activities towards entering into future clinical trials, costs to identify, isolate and advance human antibody drug candidates derived from our libraries as well as advancing our ADC preclinical drug candidates, preclinical testing expenses and the expenses associated with fulfilling our development obligations related to the NIH grant awards, collectively the NIH Grants. Such expenses consist primarily of salaries and personnel related expenses, stock-based compensation expense, clinical development expenses, preclinical testing, lab supplies, consulting costs, depreciation and other expenses. The increase of $1,804 is primarily attributable to salaries and

compensation related expense, consulting and lab supply costs incurred in connection with our expanded research and development activities and activities to advance RTX into clinical trials and potentially pursue other development. We expect research and development expenses to increase in absolute dollars as we: (i) advance RTX into clinical trials and pursue other potential indications, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to further advance a number of potential product candidates into preclinical development activities, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical product candidates, (iv) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of our programs, and (v) invest in our JV's or other third party agreements.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the three months ended September 30, 2015 and 2014 were $24,068 and $0, respectively. Acquired in-process research and development expenses for the three months ended September 30, 2015 include costs associated with the purchase price of the license rights from Mabtech Limited, the purchase price of the license rights from the City of Hope and the purchase price of CARgenix and BDL.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2015 and 2014 were $4,711 and $1,854, respectively. General and administrative expenses consist primarily of salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation expense, professional fees, infrastructure expenses, legal and accounting expenses and other general corporate expenses. The increase of $2,857 is primarily attributable to higher legal costs, higher stock-based compensation, higher salaries and related compensation expenses and rent and facility expenses partially offset by lower general corporate and IP matters and consulting and business development expenses. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, (ii) compliance with our public reporting obligations, (iii) increased infrastructure costs, and (iv) invest in our JV's or other third party agreements.

Intangible Amortization. Intangible amortization for the three months ended September 30, 2015 and 2014 was $111 and $586, respectively. The decrease in the three months ended September 30, 2015 as compared to the same period in 2014 is due to license rights being amortized on a straight line basis through the date those assets were sold.

Gain on sale of IgDraSol. Gain on sale of IgDraSol for the three months ended September 30, 2015 and 2014 was $69,274 and $0, respectively.

Interest Expense. Interest expense for the three months ended September 30, 2015 and 2014 was $396 and $476, respectively. The decrease in interest expense resulted primarily from lower average borrowings under the amended loan and security agreement.

Interest Income. Interest income for the three months ended September 30, 2015 and 2014 was $1 and $2, respectively. We expect that continued low interest rates will significantly limit our interest income in the near term.

Income tax expense. Income tax provision for the three months ended September 30, 2015 and 2014 was $35,323 and $0, respectively. The increase in income tax provision resulted mainly from the recognition of an indefinite-lived deferred tax liability.

Net Loss. Net loss for the three months ended September 30, 2015 and 2014 was $939 and $7,605, respectively. The decrease in net loss is mainly attributable to the gain on sale of IgDraSol partially offset by increased research and development activities, acquired in-process research and development expense and general and administrative expenses.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Revenues. Revenues were $3,253 for the nine months ended September 30, 2015, as compared to $3,027 for the nine months ended September 30, 2014. The net increase of $226 is primarily due to more active grants and an increase in activities under our active grants for the nine months ending September 30, 2015 compared to the same period of 2014, partially offset by lower sales and service revenues generated from the sale of customized reagents and providing contract development services.

In June 2012, we were awarded a third Advanced Technology Small Business Technology Transfer Research (STTR) grant to support our program to generate and develop novel human antibody therapeutics to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant II award. The project period for the phase I grant covers a two-year period which commenced in June 2012, with a total grant award of $600. The Staph Grant II award revenues for the nine months ended September 30, 2015 and 2014, were $0 and $150, respectively.

In June 2014, the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, or NIH awarded us a Phase II STTR grant to support the advanced preclinical development of human bispecific antibody therapeutics to prevent and treat Staphylococcus aureus (S. aureus or Staph) infections, including methicillin-resistant S. aureus (MRSA), or the Staph Grant III award. The project period for this Phase II grant covers a two-year period which commenced in June 2014, with total

funds available of approximately $1 million per year for up to 2 years. During the nine months ended September 30, 2015 and 2014, we recorded $660 and $147 of revenue, respectively, associated with the Staph Grant III award.

In June 2014, we were awarded a Phase I STTR grant entitled “Anti-Pseudomonas Immunotherapy and Targeted Drug Delivery” from the NIAID. This grant will support the preclinical development of novel anti-Pseudomonas aeruginosa mAb immunotherapy or an antibody-mediated targeted antibiotic delivery vehicle. Each modality may be an effective and safe stand-alone therapy and/or a component of a “cocktail” therapeutic option for prevention and treatment of P. aeruginosa infections. The project period for this Phase I grant covers a two-year period which commenced in July 2014, with total funds available of approximately $300 per year for up to 2 years. During the nine months ended September 30, 2015 and 2014, we recorded $167 and $11 of revenue, respectively, associated with the Phase I STTR grant award.

In July 2014, we were awarded a Phase I STTR grant from the National Cancer Institute (NCI), a division of the NIH, entitled “Targeting of Myc-Max Dimerization for the Treatment of Cancer”. This grant will support the preclinical development of the Myc inhibitor, which interferes with the protein-protein interaction (PPI) between Myc and its obligatory dimerization partner, Max, preventing sequence-specific binding to DNA and subsequent initiation of oncogenic transformation. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the nine months ended September 30, 2015 and 2014, we recorded $139 and $19 of revenue, respectively associated with the Phase I Myc grant award.

In August 2014, we were awarded a Phase I Small Business Technology Transfer (SBIR) grant from the National Heart, Lung, and Blood Institute (NHBLI), a division of the NIH, entitled “Human Anti-WISP-1 Antibodies for Treatment of Idiopathic Pulmonary Fibrosis”. This grant will advance the Company’s immunotherapy targeting WNT-1 Inducible Signaling Protein-1(WISP1) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). WISP1 is a protein that has been shown to be upregulated in IPF, linked to key growth factors, cellular proliferation, hyperplasia and is correlated with late stage cancers. IPF is a fatal disease, which results in progressive loss of lung function due to fibrosis of the lungs. The project period for this Phase I grant covers a one-year period which commenced in August 2014, with total funds available of approximately $225. During the nine months ended September 30, 2015 and 2014, we recorded $61 and $2 of revenue, respectively, associated with the Phase I WISP1 grant award

Revenues from a human immune-oncology anti PD-L1 license agreement for the nine months ended September 30, 2015 and 2014, were $37 and $0, respectively. We had no other revenue during the nine months ended September 30, 2015 and 2014 as we have not yet developed any product candidates for commercialization or earned any licensing or royalty payments

Cost of revenues. Cost of revenues for the nine months ended September 30, 2015 and 2014 were $1,427 and $1,600, respectively, and relate to the sale of customized reagents and providing contract development services. The costs generally include employee-related expenses including salary and benefits, direct materials and overhead costs including rent, depreciation, utilities, facility maintenance and insurance.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2015 and 2014 were $23,055 and $16,856, respectively. Research and development expenses include the costs related to Cynviloq prior to its sale in July 2015, costs to advance our RTX program activities towards entering into future clinical trials, costs to identify, isolate and advance human antibody drug candidates derived from our libraries as well as advancing our ADC preclinical drug candidates, preclinical testing expenses and the expenses associated with fulfilling our development obligations related to the NIH grant awards, collectively the NIH Grants. Such expenses consist primarily of salaries and personnel related expenses, stock-based compensation expense, clinical development expenses, preclinical testing, lab supplies, consulting costs, depreciation and other expenses. The increase of $6,199 is primarily attributable to preclinical testing and completion of our BE registration trial prior to its sale in July 2015, salaries and compensation related expense, consulting and lab supply costs incurred in connection with our expanded research and development activities and activities to advance RTX into clinical trials and potentially pursue other

development. We expect research and development expenses to increase in absolute dollars as we: (i) advance RTX into clinical trials and pursue other development, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to further advance a number of potential product candidates into preclinical development activities, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical product candidates, (iv) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of our programs, and (v) invest in our JV's or other third party agreements.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses for the nine months ended September 30, 2015 and 2014 were $24,068 and $209, respectively. Acquired in-process research and development expenses for the nine months ended September 30, 2015 include costs associated with the purchase price of the license rights from Mabtech Limited, the purchase price of the license rights from the City of Hope and the purchase price of CARgenix and BDL. Acquired in-process research and development expenses for the nine months ended September 30, 2014 include the costs associated with a research agreement.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2015 and 2014 were $10,002 and $7,600, respectively. General and administrative expenses consist primarily of salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation expense, professional fees, infrastructure expenses, legal and accounting expenses and other general corporate expenses. The increase of $2,402 is primarily attributable to higher salaries and related compensation expenses, stock-based compensation and legal costs related to general corporate and IP matters. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, (ii) compliance with our public reporting obligations, (iii) build our infrastructure, and (iv) invest in our JV's or other third party agreements.

Intangible Amortization. Intangible amortization for the nine months ended September 30, 2015 and 2014 was $1,046 and $1,758, respectively. The decrease in the nine months ended September 30, 2015 as compared to the same period in 2014 is due to license rights being amortized on a straight line basis through the date those assets were sold.

Gain on sale of IgDraSol. Gain on sale of IgDraSol for the nine months ended September 30, 2015 and 2014 was $69,274 and $0, respectively.

Interest Expense. Interest expense for the nine months ended September 30, 2015 and 2014 was $1,277 and $1,167, respectively. The increase in interest expense resulted primarily from higher average borrowings under the amended loan and security agreement entered into in March 2014.

Interest Income. Interest income for the nine months ended September 30, 2015 and 2014 was $1 and $11, respectively. The decrease in interest income resulted from lower average cash balances in 2015 as compared to the same period in 2014. We expect that continued low interest rates will significantly limit our interest income in the near term.

Income tax expense. Income tax provision for the nine months ended September 30, 2015 and 2014 was $35,128 and $0, respectively. The increase in income tax provision resulted mainly from the recognition of an indefinite-lived deferred tax liability and return to provision adjustments.

Net Loss. Net loss for the nine months ended September 30, 2015 and 2014 was $22,335 and $26,152, respectively. The decrease in net loss is mainly attributable to the gain on sale of IgDraSol partially offset by increased research and development activities, acquired in-process research and development expenses and general and administrative expenses.

Liquidity and Capital Resources

As of September 30, 2015, we had $59.1 million in cash and cash equivalents attributable in part to the December 2014 issuance of 7.2 million shares of our common stock for cash to Cambridge Equities in a private equity financing totaling $41.7 million and the net proceeds from the sale of IgDraSol of $27.8 million. Our working capital as of September 30, 2015 was $98.7 million.

Cash Flows from Operating Activities. Net cash used for operating activities was $25,907 for 2015 and is primarily attributable to our net loss of $23,475 partially offset by our realized gain on sale of IgDraSol and an increase in deferred tax provision, acquired in-process research and development and deferred revenue and other working capital balances of $2,679, combined with $7,622 in non-cash activities relating to stock-based compensation, depreciation and amortization expense and other non-cash activities. Net cash used for operating activities was $21,108 for 2014 and primarily reflects a net loss of $26,152, which was partially offset by $6,080 in non-cash activities relating primarily to stock-based compensation, acquired in-process research and development and depreciation expense.

We expect to continue to incur substantial and increasing losses and negative net cash flows from operating activities as we seek to expand and support our clinical and preclinical development and research activities and fund our JV's and collaborations.

Cash Flows from Investing Activities. Net cash provided by investing activities was $14,309 for 2015 as compared to cash used of $433 for 2014. The net cash provided related primarily to the net proceeds from the sale of IgDraSol partially offset by investments in common stock of a non-public entity and equipment acquired for research and development activities.

We expect to increase our investment in equipment as we seek to expand and progress our research and development capabilities.

Cash Flows from Financing Activities. Net cash used in financing activities was $1,237 for 2015 which was primarily for the payment of deferred compensation and principal payments under our amended and restated loan and security agreement partially offset by the proceeds from option exercises as compared to cash provided by financing activities of $34,143 in 2014 which was

provided by the closing of our underwritten public offerings and increases in net borrowings under our amended and restated loan and security agreement.

Future Liquidity Needs. We have principally financed our operations through underwritten public offerings and private equity financings with aggregate net proceeds of $124,938, as we have not generated any product related revenue from our principal operations to date, and do not expect to generate significant revenue for several years, if ever. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development, as well as to fund operations generally. As and if necessary, we will seek to raise additional funds through various potential sources, such as equity and debt financings, or through corporate collaboration and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

We anticipate that we will continue to incur net losses into the foreseeable future as we: (i) advance RTX into clinical trials and potentially pursue other development, (ii) continue to identify and advance a number of potential mAb and ADC product candidates into preclinical development activities, (iii) continue our development of, and seek regulatory approvals for, our product candidates, (iv) expand our corporate infrastructure, including the costs associated with being a NASDAQ listed public company, and (v) incur our share of JV and collaboration costs for our products and technologies. We believe we have the ability to meet all obligations due over the course of the next twelve months.

We plan to continue to fund our operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. We filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission (“SEC”), which was declared effective by the SEC in July 2013. The Shelf Registration Statement provides us the ability to offer up to $100 million of securities, including equity and other securities as described in the registration statement. After the May 2014 underwritten offering, we have the ability to offer up to $36.6 million of additional securities. In November 2014, we filed an additional universal shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC in December 2014. This Shelf Registration Statement provides us with the ability to offer up to $250 million of securities, including equity and other securities as described in the registration statement. Included in the November 2014 shelf registration is a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $50 million of our common stock that may be issued and sold under a sales agreement with MLV & Co. LLC. Pursuant to these Shelf Registration Statements, we may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and our capital needs. Specific terms and prices will be determined at the time of each offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. However, we cannot be sure that such additional funds will be available on reasonable terms, or at all. If we are unable to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Any of these actions could materially harm our business, results of operations, and future prospects.

If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Off-Balance Sheet Arrangements

Since our inception through September 30, 2015, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

New Accounting Pronouncements

Refer to Note 1, “Nature of Operations, Summary of Significant Accounting Polices and Business Activities,” in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk. Our exposure to market risk is confined to our cash and cash equivalents. We have cash and cash equivalents and invest primarily in high-quality money market funds, which we believe are subject to limited credit risk. Due to the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Our amended and restated loan and security agreement has a fixed interest rate of 7.95% per annum through the loan maturity. We do not believe that we have any material exposure to interest rate risk arising from our investments.

Capital Market Risk. We currently do not have significant revenues from grants or sales and services and we have no product revenues from our planned principal operations and therefore depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price.

Item 4. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's regulations, rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal 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 Rule 13a-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal 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 Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.
To the best of our knowledge, we are not a party to any legal proceedings that, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

Item 1A. Risk Factors.
Risks Related to Our Financial Position and Capital Requirements

We are a development-stage company subject to significant risks and uncertainties, including the risk that we or our partners may never develop, obtain regulatory approval or market any of our product candidates or generate product related revenues.

We are a development-stage biopharmaceutical company that began operating and commenced research and development activities in 2009. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. There is no assurance that our libraries of fully-human mAbs will be suitable for diagnostic or therapeutic use, or that we will be able to identify and isolate therapeutics product candidates, or develop, market and commercialize these candidates. We do not expect any of our fully-human mAb, ADC, RTX, biosimilar/biobetter antibodies, or related companion diagnostic product candidates to be commercially available for a few years, if at all. Even if we are able to commercialize our product candidates, there is no assurance that these candidates would generate revenues or that any revenues generated would be sufficient for us to become profitable or thereafter maintain profitability.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of September 30, 2015, December 31, 2014, 2013 and 2012, we had an accumulated deficit of $89.9 million, $67.5 million, $32.9 million and $11.0 million, respectively. We continue to incur significant research and development and other expenses related to our ongoing and acquired operations. We have incurred operating losses since our inception, expect to continue to incur significant operating losses for the foreseeable future, and we expect these losses to increase as we: (i) advance RTX into clinical trials and potentially pursue other human or veterinary indications, (ii) continue to identify and advance a number of potential mAb and ADC drug candidates into preclinical and clinical development activities, (iii) continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, and (iv) expand our corporate infrastructure, including the costs associated with being a NASDAQ public company. As such, we are subject to all risks incidental to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. 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 will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of

our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including:

- the progress of the development of our fully-human mAb, ADC, RTX, biosimilar/biobetter antibodies or related companion diagnostic product candidates;

- the number of product candidates we pursue;

- the time and costs involved in obtaining regulatory approvals;

- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

- our plans to establish sales, marketing and/or manufacturing capabilities;

- the effect of competing technological and market developments;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;

- general market conditions for offerings from biopharmaceutical companies;

- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and

- our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Further, there is uncertainty related to future NIH grant funding, and the NIH plans for new grants or cooperative agreements may be re-scoped, delayed, or canceled depending on the nature of the work and the availability of resources. As a result, we cannot assure you that we will receive any additional funding under our existing NIH grants, and we may not be successful in securing additional grants from the NIH in the future.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our technologies and product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

·developing our technology platform;

·identifying, developing, manufacturing and commercializing product candidates;

·entering into successful licensing and other arrangements with product development partners;

· participating in regulatory approval processes;

· formulating and manufacturing products; and

·conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining early preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is risky and uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the pharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

We have not previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate, including our planned clinical trials of RTX, and our biosimilar/biobetters antibodies in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

In the event we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life-threatening diseases, in some cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are

not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival or complete response rate, the FDA may refuse to approve a BLA based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to RTX, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

·obtaining regulatory approval to commence a trial;

- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites,

  the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- obtaining institutional review board, or IRB, approval at each site;

- recruiting suitable patients to participate in a trial;

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

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

- developing and validating companion diagnostics on a timely basis, if required;

- adding new clinical trial sites; or

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

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our potential drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory

approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the U.S., the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Our approach to the discovery and development of product candidates that target ADCs is unproven, and we do not know whether we will be able to develop any products of commercial value.

ADCs are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable products to treat human patients with cancer or other diseases.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In

such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

·regulatory authorities may withdraw approvals of such products;

·regulatory authorities may require additional warnings on the label;

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

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

·our reputation may suffer.

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

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and

except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP regulatory requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Material necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on our manufacturers to produce or purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. We currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with all of our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

We are dependent on our third party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to

secure alternate suppliers. While we believe that there are other contract manufacturers having the technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the U.S. to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the U.S., we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate

with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidates in international markets.

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. The future discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and

- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing

requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if we believe the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

- increased amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;

- inability to motivate key employees of any acquired businesses; and

- assumption of known and unknown liabilities.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

· the efficacy and safety as demonstrated in clinical trials;

· the timing of market introduction of such product candidate as well as competitive products;

· the clinical indications for which the drug is approved;

· acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

· the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;

· the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

· the availability of adequate reimbursement and pricing by third-party payors and government authorities;

· the product labeling or product insert required by the FDA or regulatory authority in other countries;

· the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;

·the prevalence and severity of adverse side effects; and

·the effectiveness of our sales and marketing efforts.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

If we cannot compete successfully against other biotechnology and pharmaceutical companies, we may not be successful in developing and commercializing our technology and our business will suffer.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid technological advances, both in the U.S. and internationally. In addition, the competition in the oncology market is intense. Even if we are able to develop our proprietary platform technology and additional antibody libraries, each will compete with a number of existing and future technologies and product candidates developed, manufactured and marketed by others. Specifically, we will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have validated technologies with products already FDA-approved or in various stages of development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

·developing product candidates and technologies generally;

·undertaking preclinical testing and clinical trials;

·obtaining FDA and other regulatory approvals of product candidates;

·formulating and manufacturing product candidates; and

·launching, marketing and selling product candidates.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies or generic pharmaceutical manufacturers may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more

effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business. If our technologies fail to compete effectively against third party technologies, our business will be adversely impacted.

We expect that our ability to compete effectively will depend upon our ability to:

· successfully and efficiently complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

· maintain a proprietary position for our products and manufacturing processes and other related product technology;

·attract and retain key personnel;

·develop relationships with physicians prescribing these products; and

·build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the U.S., Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In both the U.S. and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the U.S. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

Certain of our potential product candidates are in early stages of development and any product candidates that we develop will require extensive preclinical and clinical testing before they are approved by the appropriate regulatory agency, if at all.

The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. We are in the early stages of developing potential product candidates, and any candidates that we develop will require extensive preclinical and clinical testing

before they will be approved by the FDA or another regulatory authority in a jurisdiction outside the U.S., if at all. We have not yet developed any product candidate; if we were to do so there are a number of requirements that we would be required to satisfy in order to begin conducting preclinical trials and there can be no assurance that we will develop product candidates or complete the steps necessary to allow us to commence these trials. We cannot predict with any certainty the results of preclinical testing or whether such trials would yield sufficient data to permit us, or those with whom we collaborate, to proceed with clinical development and ultimately submit an application for regulatory approval of our product candidates in the U.S. or abroad, or whether such applications would be approved by the appropriate regulatory agency. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our long-term drug development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patients within a disease category or indication who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular category or indication, both during our clinical trials and in connection with the commercialization of certain of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

Our collaborations depend upon the efforts of third parties to fund and manage the development of many of our potential product candidates, and failure of those third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary product candidates has included the formation of joint ventures and collaborative arrangements with third parties. Potential third parties include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

·funding research, preclinical development, clinical trials and manufacturing;

·seeking and obtaining regulatory approvals; and

·successfully commercializing any future product candidates.

Our collaborations limit our ability to control the efforts devoted to many of our product candidates in such arrangements and our earlier stage pipeline is dependent upon identifying new potential collaborators. For example, our most recent joint ventures require us to conduct research and provide potential product candidates in addition to making capital contributions to continue the further development of those products. We do not have control over the management of the joint ventures and are minority holders in most of those ventures, which may result in limitations on our ability to successfully develop product candidates and fund clinical trials through those joint ventures.

In addition, if we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources.

Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Adverse economic conditions may have material adverse consequences on our business, results of operations and financial condition.

Unpredictable and unstable changes in economic conditions, including recession, inflation, increased government intervention, or other changes, may adversely affect our general business strategy. We rely upon our ability to generate additional sources of liquidity and we may need to raise additional funds through public or private debt or equity financings in order to fund existing operations or to take advantage of opportunities, including acquisitions of complementary businesses or technologies. Any adverse event would have a material adverse impact on our business, results of operations and financial condition.

Because our development activities are expected to rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.

Although we are not subject to HIPAA, as neither a Covered Entity nor Business Associate (as defined in HIPAA and the HITECH Act), we may have access to very sensitive data regarding patients whose tissue samples are used in our studies. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, create national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to achieve profitability or maintain profitably in the future.

Our therapeutic product candidates for which we intend to seek approval as biological products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable." The FDA defines an interchangeable biosimilar as a product that, in terms of safety or diminished efficacy, presents no greater risk when switching between the biosimilar and its reference product than the risk of using the reference product alone. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA. The new law is complex and is only beginning to be interpreted by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego

the biosimilar route and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. We do not currently maintain hazardous materials insurance coverage. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially harm our business.

If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business.

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the successful development of any product candidates, our ability to raise additional capital and our ability to implement our overall business strategy.

We are highly dependent on key members of our management and scientific staff, especially Henry Ji, Ph.D, Chief Executive Officer and President, and Mike Royal, Executive Vice President of Clinical and Regulatory Affairs. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel. The loss of any of our executive officers, key employees or key consultants and our inability to find suitable replacements could impede the achievement of our research and development objectives, potentially harm our business, financial condition and prospects. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. Certain of our current officers, directors, scientific advisors and/or consultants or certain of the officers, directors, scientific advisors and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors and/or consultants of other biopharmaceutical or biotechnology companies. We do not maintain “key man” insurance policies on any of our officers or employees. All of our employees are employed “at will” and, therefore, each employee may leave our employment at any time.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We plan to grant stock options or other forms of equity awards in the future as a method of attracting and retaining employees, motivating performance and aligning the interests of employees with those of our stockholders. If we are unable to implement and maintain equity compensation arrangements that provide sufficient incentives, we may be unable to retain our existing employees and attract additional qualified candidates. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, our business and results of operations could be adversely affected.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and

regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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

· decreased demand for our product candidates or products that we may develop;

· injury to our reputation;

· withdrawal of clinical trial participants;

· initiation of investigations by regulators;

·costs to defend the related litigation;

·a diversion of management's time and our resources;

·substantial monetary awards to trial participants or patients;

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

·loss of revenues from product sales; and

·the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to certain anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and other anti-corruption laws that apply in countries where we do business. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered in the U.S. and in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, "Trade Control Laws").

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws, including the FCPA or other legal requirements, such as Trade Control Laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by U.S., EU or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, results of operations and financial condition.

We will need to increase the size of our company and may not effectively manage our growth.

Our success will depend upon growing our business and our employee base. Over the next 12 months, we plan to add additional employees to assist us with research and development. Our future growth, if any, may cause a significant

strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition, and results of operations.

Any disruption in our research and development facilities could adversely affect our business, financial condition and results of operations.

Our principal executive offices, which house our research and development programs, are located in San Diego, California. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that our facilities were affected by a natural or man-made disaster, we may be forced to curtail our operations and/or rely on third-parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

If we acquire companies or technologies in the future, they could prove difficult to integrate, disrupt our business, dilute stockholder value, and adversely affect our operating results and the value of our common stock.

As part of our business strategy, we may acquire, enter into joint ventures with, or make investments in complementary or synergistic companies, services, and technologies in the future. Acquisitions and investments involve numerous risks, including:

·difficulties in identifying and acquiring products, technologies, or businesses that will help our business;

·difficulties in integrating operations, technologies, services, and personnel;

·diversion of financial and managerial resources from existing operations;

·the risk of entering new development activities and markets in which we have little to no experience;

·risks related to the assumption of known and unknown liabilities; and

·risks related to our ability to raise sufficient capital to fund additional operating activities.

As a result, if we fail to properly evaluate acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, we may incur costs in excess of what we anticipate, and management resources and attention may be diverted from other necessary or valuable activities.

The terms of our secured debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Effective in March 2014, as amended and restated, we entered into a $12.5 million loan and security agreement with Oxford Finance and Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of December 31, 2014, we had an outstanding principal balance of $12.5 million. The amended and restated loan and security agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender’s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default

through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Acquisitions

We have and plan to continue to acquire businesses and technologies and may fail to realize the anticipated benefits of the acquisitions, and acquisitions can be costly and dilutive.

In the past 2 years, we acquired three companies. The success of any acquisitions depend on, among other things, our ability to combine our businesses in a manner that does not materially disrupt existing relationships and that allows us to achieve development and operational synergies. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value or development pipeline in the near or long term.

It is possible that the integration process could result in the loss of key employees; the disruption of our ongoing business or the ongoing business of the acquired companies; or inconsistencies in standards, controls, procedures, or policies that could adversely affect our ability to maintain relationships with third parties and employees or to achieve the anticipated benefits of the acquisition. Integration efforts between the two companies will also divert management's attention from our core business and other opportunities that could have been beneficial to our stockholders. An inability to realize the full extent of, or any of, the anticipated benefits of the acquisition, as well as any delays encountered in the integration process, could have an adverse effect on our business and results of operations, which may affect the value of the shares of our common stock after the completion of the acquisition. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value or development pipeline in the near or long term.

During 2013, for example, we incurred significant legal and professional fees in connection with such acquisitions. We expect to incur additional costs integrating the companies' operations, higher development and regulatory costs, and personnel, which cannot be estimated accurately at this time. If the total costs of the integration of our companies and advancement of acquired product candidates and technologies such as RTX and Concortis assets exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

Risks Related to Our Intellectual Property

Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the U.S. or abroad.

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We have one issued U.S. patent covering our G-MAB® which expires in 2022 and the examination of its European equivalent is currently in progress. In 2011, several improvement patent applications were filed for our proprietary antibody library technology. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. In 2013 and 2014, we filed 18 antibody family patent applications. The first of the antibody family patents applications issued on October 14, 2014 as U.S. Patent 8,859,740. In 2013 and 2014, we filed five patent application families for the Concortis

conjugation chemistry associated with ADC's.

We have commenced generating a patent application portfolio of patents to protect each product candidate in our pipeline. However, the patent position of biopharmaceutical companies involves complex legal and factual questions, and therefore we cannot predict with certainty whether any patent applications that we have filed or that we may file in the future will be approved or any resulting patents will be enforced. In addition, third parties may challenge, seek to invalidate or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Any patent applications that we have filed or that we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies.

In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the US. If we fail to apply for intellectual property protection or if we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more effectively against us, which could adversely affect our competitive position, as well as our business, financial condition and results of operations.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel and our consultants and advisors, as well as our licensors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. Unlike some of our competitors, in addition to certain manufacturing processes, we maintain our proprietary libraries for ourselves as trade secrets, as we believe they have proven to be superior in obtaining strong binder product candidates. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Third party competitors may seek to challenge the validity of our patents, thereby rendering them unenforceable or we may seek to challenge third party competitor patents if such third parties seek to interpret or enforce a claim scope going well beyond the actual enabled invention.

Claims that we infringe upon the rights of third parties may give rise to costly and lengthy litigation, and we could be prevented from selling products, forced to pay damages, and defend against litigation.

Third parties may assert patent or other intellectual property infringement claims against us or our strategic partners or licensees with respect to our technologies and potential product candidates. If our products, methods, processes and other technologies infringe upon the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all, and may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us;

- redesign our products or processes to avoid infringement;

- stop using the subject matter validly claimed in the patents held by others;

- pay damages; and

- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our strategic partners or licensees, we or our strategic partners or licensees may be forced to stop or delay developing, manufacturing or selling technologies or potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our strategic partners' or licensees' rights to use its intellectual property. Ultimately, we may be unable to develop some of our technologies or potential products or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent

infringement claims, which could severely harm our business.

Our position as a relatively small company may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against infringement claims by third parties.

Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that our technology infringes or misappropriates third party intellectual property rights. However, we may seek to use various post-grant administrative proceedings, including new procedures created under the America Invents Act, to invalidate potentially overly-broad third party rights. Even if we are able to defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. Although we have not yet experienced patent litigation, we may in the future be subject to such litigation and may not be able to protect our intellectual property at a reasonable cost, or at all, if such litigation is initiated. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including Patent Office administrative proceedings, such as inter parties reviews, and reexamination proceedings before the U.S. PTO or oppositions and revocations and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Despite safe harbor provisions, third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware, with claims to materials, formulations, methods of doing research or library screening, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent published applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party’s relationship with us. We also typically obtain agreements from these parties which provide

that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part.

Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;

- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions;

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- It is possible that our pending patent applications will not lead to issued patents;

- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

· We may not develop additional proprietary technologies that are patentable; and

· The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party's proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

We remain subject to the Exclusive Distribution Agreement with Samyang Biopharmaceuticals Corporation and are required to pay all milestone and license fees pursuant to such agreement.

As a result of our acquisition of IgDraSol Inc.in September 2013, we became a party to an Exclusive Distribution Agreement, as amended, with Samyang Biopharmaceuticals Corporation, or Samyang, in connection with our development of Cynviloq which contained various milestone and license fees to be paid to Samyang. On May 14, 2015, we sold all of our equity interests in IgDrasol

Inc. to NantPharma, LLC, or NantPharma. As part of the sale, we agreed with NantPharma to be responsible for and pay all milestone and license fees required to be paid to Samyang under the Exclusive Distribution Agreement following notification from NantPharma when such milestone and license fees become due and payable. While there are milestone payments to be paid to us from NantPharma as part of the sale of IgDraSol, in the event milestone payments are not paid to us, we will still be responsible for any and all milestone and license fees to be paid to Samyang pursuant to the Exclusive Distribution Agreement.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may fluctuate significantly, and investors in our common stock may lose all or a part of their investment.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

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

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

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

- adverse regulatory decisions;

- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;

- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates, government investigations and the results of any proceedings or lawsuits, including patent or stockholder litigation;

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

- our dependence on third parties, including CROs;

- announcements of the introduction of new products by our competitors;

- market conditions in the pharmaceutical and biotechnology sectors;

- announcements concerning product development results or intellectual property rights of others;

- future issuances of common stock or other securities;

- the addition or departure of key personnel;

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

- actual or anticipated variations in quarterly operating results;

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

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

- conditions or trends in the biotechnology and biopharmaceutical industries;

- introduction of new products offered by us or our competitors;

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

- issuances of debt or equity securities;

- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;

- ineffectiveness of our internal controls;

- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research

coverage by securities analysts;

- failure to effectively integrate the acquired companies operations;

- general political and economic conditions;

- effects of natural or man-made catastrophic events; and

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

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock might worsen if the trading volume of our common stock is low. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

Our strategic investments may result in losses.

We periodically make strategic investments in various public and private companies with businesses or technologies that may complement our business. The market values of these strategic investments may fluctuate due to market conditions and other conditions over which we have no control. Other-than-temporary declines in the market price and valuations of the securities that we hold in other companies would require us to record losses related to our investment. This could result in future charges to our earnings. It is uncertain whether or not we will realize any long-term benefits associated with these strategic investments.

Dr. Patrick Soon-Shiong, one of our principal stockholders, has significant interests in other companies which may conflict with our interests.

One of our principal stockholders, Dr. Patrick Soon-Shiong, is the founder of NantWorks, Inc., and a large stockholder in NantKwest, Inc. Both NantKwest and the various NantWorks companies are currently exploring opportunities in the immunotherapy, infectious disease and inflammatory disease fields. As a result, they or other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in the other therapeutic fields in which we may target in the future). As a result Dr. Soon-Shiong's interests may not be aligned with our other stockholders and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do

not view as being in their interest as investors in our company. Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us.

A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, substantial amounts of our common stock in the public market, including shares issued in connection with the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of our securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;

- the addition or termination of clinical trials;

- any intellectual property infringement lawsuit in which we may become involved;

- regulatory developments affecting our product candidates; and

- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

Existing stockholders' interest in us may be diluted by additional issuances of equity securities and raising funds through acquisitions, lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may issue additional equity securities to fund future expansion and pursuant to employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as our common stock or, alternatively, may have dividend, liquidation or other preferences to our common stock. The issuance of additional equity securities will dilute the holdings of existing stockholders and may reduce the share price of our common stock.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product candidates.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interests or those of our other stockholders.

As of September 30, 2015, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, approximately 30.3% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert significant influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

Our ability to use our net operating loss carry forwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us.

Our certificate of incorporation, as amended, and bylaws provide for indemnification of officers and directors at our expense and limits their liability, which may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of our officers and/or directors.

Our certificate of incorporation, as amended, bylaws and applicable Delaware law provide for the indemnification of our directors, officers, employees, and agents, under certain circumstances, against attorney's fees and other expenses incurred by them in any litigation to which they become a party arising from their association with or activities on our behalf. We will also bear the expenses of such litigation for any of our directors, officers, employees, or agents, upon such person's promise to repay us, therefore if it is ultimately determined that any such person shall not have been entitled to indemnification. This indemnification policy could result in substantial expenditures by us, which we will be unable to recover.

Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company, prevent attempts to replace or remove current management and reduce the market price of our common stock.

Provisions in our certificate of incorporation, as amended, and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our certificate of incorporation, as amended, authorizes our board of directors to issue up to 100,000,000 shares of "blank check" preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Delaware General Corporation Law. Under these provisions, if anyone becomes an "interested stockholder," we may not enter into a "business combination" with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change in control of us. An "interested stockholder" means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock within the past three years, subject to certain exceptions as described in the Delaware General Corporation Law.

We have adopted a shareholder rights plan, the purpose of which is, among other things, to enhance our Board's ability to protect shareholder interests and to ensure that stockholders receive fair treatment in the event any coercive takeover attempt of our company is made in the future. The shareholder rights plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our common stock.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, new regulations promulgated by the SEC and rules promulgated by the national securities exchanges. The Dodd-Frank Act, enacted in July 2010, expands federal regulation of corporate governance matters and imposes requirements on public companies to, among other things, provides stockholders with a periodic advisory vote on executive compensation and also adds compensation committee reforms and enhanced pay-for-performance disclosures. While some provisions of the Dodd-Frank Act are effective upon enactment, others will be implemented upon the SEC's adoption of related rules and regulations. The scope and timing of the adoption of such rules and regulations is uncertain and, accordingly, the cost of compliance with the Dodd-Frank Act is also uncertain.

These new or changed laws, regulations and standards are, or will be, subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Members of our board of directors and our principal executive officer and principal financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified directors and executive officers, which could harm our business. If the actions we take in our efforts to comply with new or changed laws, regulations and standards differ from the actions intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Sarbanes-Oxley specifically requires, among other things, that we maintain effective internal controls for financial reporting and disclosure of controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of Sarbanes-Oxley. Our testing, or the subsequent testing by our independent registered public accounting firm, if and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Quarterly Report on Form 10-Q and such Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements 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.

Sorrento Therapeutics, Inc.

Date: November 13, 2015	By:	/s/ Henry Ji, PH.D. Henry Ji, Ph.D. Director, Chief Executive Officer & President (Principal Executive Officer)
Date: November 13, 2015	By:	/s/ Douglas Langston Douglas Langston Vice President of Finance (Principal Financial and Accounting Officer)

EXHIBIT INDEX

10.1	Membership Interest Purchase Agreement by and among TNK Therapeutics, Inc., CARgenix Holdings LLC, the Members of CARgenix Holdings LLC, Jaymin Patel as the Members Representative and Sorrento Therapeutics, Inc. dated as of August 7, 2015**.
10.2	Stock Purchase Agreement by and among TNK Therapeutics, Inc., BDL Products, Inc., the Stockholders of BDL Products, Inc., Richard Junghans, M.D., Ph.D. as the Stockholders' Representative and Sorrento Therapeutics, Inc. dated as of August 7, 2015**.
10.3	Binding Term Sheet with NanoVelcro Circulating Tumor Cell
10.4	Exclusive License Agreement dated September 25, 2015 by and between LA Cell, Inc. and City of Hope*
31.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Douglas Langston, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, and Douglas Langston, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
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

*Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

**Sorrento hereby undertakes to furnish supplementally a copy of any omitted schedule or exhibit to such agreement to the U.S. Securities and Exchange Commission upon request.