Sorrento Therapeutics, Inc.
Form 10-Q/A
April 01, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to

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.

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EXPLANATORY NOTE

This Amendment No. 1 on Form 10-Q/A amends our original Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015 filed on November 16, 2015 (the Original Filing). The sole purpose of this Amendment No. 1 is to include the number of shares of a subsidiary of the Company issued pursuant to a license agreement.

Except as described above, this Amendment No. 1 does not amend, update or change any other items or disclosures contained in the Original Filing as amended by this Amendment No. 1, and accordingly, this Amendment No. 1 does not reflect or purport to reflect any information or events occurring after the original filing date or modify or update those disclosures affected by subsequent events. Accordingly, this Amendment No. 1 should be read in conjunction with our other filings with the SEC.

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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

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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

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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

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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

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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.

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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

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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

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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.

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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.

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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).

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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

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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

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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

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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

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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.

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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

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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 Exercise Price	Aggregate Intrinsic Value
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

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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. In addition, pursuant the license agreement, LA Cell issued to City of Hope 2,648,948 shares of its Class C Common Stock.

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

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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.

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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. Because 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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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.

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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;

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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;

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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.

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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

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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.

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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.

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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 t