Sorrento Therapeutics, Inc.
Form 10-Q
November 14, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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)**

6042 Cornerstone Ct. West,

Suite B

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

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 8, 2013 was 21,678,353.

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Sorrento Therapeutics, Inc.

(a Development Stage Company)

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

	September 30, 2013 (Unaudited)	December 31, 2012 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,429,712	$ 5,091,312
Grants receivable	36,564	79,760
Prepaid expenses and other, net	407,560	80,918
Total current assets	6,873,836	5,251,990
Property and equipment, net	1,661,551	1,480,989
Intangibles, net	28,994,423	
Other, net	452,805	48,625
Total assets	$ 37,982,615	$ 6,781,604
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,407,516	$ 439,533
Accrued payroll and related	808,568	77,744
Accrued expenses	102,387	66,896
Total current liabilities	2,318,471	584,173
Long-term debt	4,785,320	
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par value; 100,000,000 shares authorized and no shares issued and outstanding		
Common stock, $0.0001 par value; 750,000,000 shares authorized and 16,479,734 and 12,004,687 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	1,648	1,200
Additional paid-in capital	52,442,871	17,146,530
Deficit accumulated during the development stage	(21,565,695)	(10,950,299)
Total stockholders equity	30,878,824	6,197,431
Total liabilities and stockholders equity	$ 37,982,615	$ 6,781,604

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from January 25, 2006 (Inception) through September 30,
	2013	2012	2013	2012	2013
Revenues:					
Grant	$ 83,791	$ 134,506	$ 359,451	$ 461,790	$ 1,931,524
Collaboration and reimbursable research and development costs					223,453
Total revenues	83,791	134,506	359,451	461,790	2,154,977
Expenses:					
Research and development	2,082,252	950,823	5,621,969	2,667,347	13,825,295
Acquired in-process research and development			1,210,000		1,210,000
General and administrative	1,114,621	427,030	3,752,233	890,262	8,323,626
Intangibles amortization	193,755		313,339		313,339
Total expenses	3,390,628	1,377,853	10,897,541	3,557,609	23,672,260
Loss from operations	(3,306,837)	(1,243,347)	(10,538,090)	(3,095,819)	(21,517,283)
Interest expense	(51,285)		(82,975)		(82,975)
Interest income	1,677	2,118	5,669	5,346	34,563
Net loss	$ (3,356,445)	$ (1,241,229)	$ (10,615,396)	$ (3,090,473)	$ (21,565,695)
Net loss per share basic and diluted	$ (0.24)	$ (0.10)	$ (0.80)	$ (0.28)	
Weighted average number of shares during the period basic and diluted	14,135,261	11,963,699	13,303,581	11,210,899	

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Stockholder Note Receivable	Deficit Accumulated During the Development Stage	Total
Balance, January 25, 2006 (Inception)		$	$	$	$	$
Issuance of common stock for $400 cash to founders	4,077,493	408	(8)			400
Net loss					(75,801)	(75,801)
Balance, December 31, 2006	4,077,493	408	(8)		(75,801)	(75,401)
Net loss					(16,302)	(16,302)
Balance, December 31, 2007	4,077,493	408	(8)		(92,103)	(91,703)
Net loss					(25,745)	(25,745)
Balance, December 31, 2008	4,077,493	408	(8)		(117,848)	(117,448)
Issuance of restricted common stock for $291 cash to consultants in March	296,155	30	261			291
Issuance of common stock for $10 cash and a $30 note to consultants in March	40,775	4	36	(30)		10
Issuance of common stock for cash at $0.98 per share in June, net of issuance costs of $25,999	2,360,611	236	2,273,765			2,274,001
Issuance of common stock for cash at $1.12 per share in September	1,785,375	179	1,999,821			2,000,000
Issuance of common stock to former QuikByte stockholders in connection with the Merger	442,958	44	100,342			100,386
Costs associated with the Merger			(168,767)			(168,767)
Stock-based compensation			54,524			54,524
Net loss					(942,266)	(942,266)
Balance, December 31, 2009	9,003,367	901	4,259,974	(30)	(1,060,114)	3,200,731
Collection of note receivable				30		30
Issuance of common stock for cash at $3.50 per share in December, net of issuance costs of $159,905	1,028,686	102	3,440,393			3,440,495
Stock-based compensation			250,954			250,954
Net loss					(1,808,386)	(1,808,386)
Balance, December 31, 2010	10,032,053	1,003	7,951,321		(2,868,500)	5,083,824
Repurchase of common stock	(44,166)	(5)	(38)			(43)
Issuance of common stock in connection with the exercise of stock options	6,000	1	13,124			13,125
Issuance of common stock for cash at $4.00 per share in December, net of issuance costs of $28,999	500,000	50	1,970,951			1,971,001
Reduction of stock issuance costs accrued in December 2010			80,039			80,039
Stock-based compensation			298,034			298,034

Net loss					(3,236,491)	(3,236,491)
Balance, December 31, 2011	10,493,887	1,049	10,313,431		(6,104,991)	4,209,489
Issuance of common stock in connection with the exercise of stock options	10,800	1	36,091			36,092
Issuance of common stock for cash at $4.00 per share in May, net of issuance costs of $65,969	1,500,000	150	5,933,881			5,934,031
Stock-based compensation			863,127			863,127
Net loss					(4,845,308)	(4,845,308)
Balance, December 31, 2012	12,004,687	1,200	17,146,530		(10,950,299)	6,197,431
Issuance of common stock in connection with the exercise of stock options	2,000		7,000			7,000
Issuance of common stock for cash at $4.50 per share in March, net of issuance costs of $64,086	1,426,406	143	6,354,266			6,354,409
Issuance of common stock in connection with assignment agreement	10,000	1	39,999			40,000
Issuance of common stock in connection with IgDraSol merger at $9.25 per share	3,006,641	301	27,811,128			27,811,429
Issuance of common stock in connection with Sherrington acquisition at $8.25 per share	30,000	3	247,497			247,500
Issuance of common stock warrants in connection with loan and security agreement			214,680			214,680
Stock-based compensation			621,771			621,771
Net loss					(10,615,396)	(10,615,396)
Balance, September 30, 2013	16,479,734	$ 1,648	$ 52,442,871	$	$ (21,565,695)	$ 30,878,824

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,		Period from January 25, 2006 (Inception) through September 30, 2013
	2013	2012	
Operating activities			
Net loss	$ (10,615,396)	$ (3,090,473)	$ (21,565,695)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	637,648	209,038	1,116,337
Stock-based compensation	621,771	290,072	2,088,410
Non-cash interest expense	35,324		35,324
Changes in operating assets and liabilities, net of acquisition:			
Grants receivable	43,196	(24,838)	(36,564)
Prepaid expenses and other	(348,421)	(36,947)	(457,815)
Accounts payable	824,878	169,786	1,001,824
Accrued expenses and other liabilities	(477,452)	15,119	(252,773)
Net cash used for operating activities	(9,278,452)	(2,468,243)	(18,070,952)
Investing activities			
Purchases of property and equipment	(359,327)	(491,096)	(2,081,043)
Purchase of intangible assets	(511,065)		(511,065)
Cash acquired in connection with Merger	125,835		230,695
Net cash used for investing activities	(744,557)	(491,096)	(2,361,413)
Financing activities			
Proceeds from issuance of common stock, net of issuance costs	6,354,409	5,934,031	21,805,860
Proceeds from exercise of stock options	7,000	4,200	56,217
Net borrowings under debt agreements	5,000,000		5,000,000
Net cash provided by financing activities	11,361,409	5,938,231	26,862,077
Net change in cash and cash equivalents	1,338,400	2,978,892	6,429,712
Cash and cash equivalents at beginning of period	5,091,312	3,466,549	
Cash and cash equivalents at end of period	$ 6,429,712	$ 6,445,441	$ 6,429,712
Supplemental disclosure:			
Cash paid during the period for:			
Income taxes	$ 800	$ 800	$ 5,600
Interest	$ 47,650	$	$ 47,650
Non-cash investing activities:			

In January 2013, a portion of the Company s purchased patent rights were from the issuance of 10,000 shares of common stock valued at $40,000.

In September 2013, the Company issued 30,000 shares of common stock valued at $0.2 million to secure rights to acquire Sherrington Pharmaceuticals, Inc., which is recorded in other assets. See Note 7.

In September 2013, the Company issued 3,006,641 shares of common stock valued at $27.8 million to effect the IgDraSol merger. See Note 3.

See accompanying notes

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SORRENTO THERAPEUTICS, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2013

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

Nature of Operations and Basis of Presentation

Sorrento Therapeutics, Inc., together with its wholly-owned subsidiaries (collectively, the Company) is a biopharmaceutical company focused on the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs in the United States, Europe and additional international markets. 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 inflammation, metabolic disorders, and infectious diseases. The Company s pipeline consists of its lead oncology product candidate Cynviloq , a micellar paclitaxel formulation, resiniferatoxin, a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor, as well as fully human therapeutic antibodies derived from our proprietary G-MAB® library platform and antibody drug conjugates, or ADCs, antibody formulated drug conjugates, or AfDCs, and recombinant intravenous immunoglobulin, or rIVIG. See Note 7.

Through September 30, 2013, the Company had devoted substantially all of its efforts to product development, acquiring companies and in-licensing assets, raising capital and building infrastructure, and had not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

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 generally accepted accounting principles in the U.S., or GAAP.

The balance sheet at December 31, 2012 is derived from the audited consolidated balance sheet at that date which is 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, 2012. Operating results for interim periods are not expected to be indicative of operating results for the Company s 2013 fiscal year.

Reverse Stock Split

On July 30, 2013, the Company completed a 1-for-25 reverse split of its common stock. All common shares and per common share amounts in the financial statements and footnotes have been adjusted retroactively to reflect the effects of this action.

Business Activities

On September 21, 2009, QuikByte Software, Inc., a shell company (QuikByte) acquired Sorrento Therapeutics, Inc., a privately held Delaware corporation (STI), in a reverse merger (the Reverse Merger). Pursuant to the Reverse Merger, all of the issued and outstanding shares of STI common stock were exchanged into an aggregate of 6,775,032 shares of QuikByte common stock and STI became a wholly owned subsidiary of QuikByte. The holders of QuikByte s common stock as of immediately prior to the Reverse Merger held an aggregate of 2,228,332 shares of QuikByte s common stock. STI and QuikByte reincorporated in Delaware in December 2009, and on December 4, 2009, STI merged with and into QuikByte, the separate corporate existence of STI ceased and QuikByte continued as the surviving corporation. Contemporaneously, QuikByte Software, Inc. changed its name to Sorrento Therapeutics, Inc. In connection with the Reverse Merger, the Company received cash of $104,860.

In January 2013, the Company entered into an assignment agreement (the assignment agreement) with Tien-Li Lee, M.D. and Jane Wu Lee, M.D. as individuals (collectively, the Lees) pursuant to which the Lees agreed to assign to the Company their right, title and interest throughout the world in and to certain inventions and patents that provide for the production of recombinant intravenous immunoglobulins. See Note 2.

On March 7, 2013, the Company entered into various agreements with IgDraSol, Inc. (IgDraSol) a private company focused on the development of Cynviloq, an oncologic agent for the treatment of metastatic breast cancer, or MBC, non-small cell lung cancer, or NSCLC, and other cancers, as follows: (i) an exclusive option agreement, (ii) an asset purchase agreement pursuant to which the Company agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies, and (iii) an initial services agreement, pursuant to which, IgDraSol is to provide certain product development and technology services related to the Company s antibody platform. See Note 3.

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Liquidity

As reflected in the accompanying consolidated financial statements, the Company has incurred operating losses since its inception in 2006, and as of September 30, 2013, had an accumulated deficit of $21,565,695. At September 30, 2013, the Company had working capital of $4,555,365.

The Company anticipates that it will continue to incur net losses into the foreseeable future as it: (i) advances its Cynviloq™ asset into a registration trial (a single bioequivalence study) and pursues other potential indications, (ii) acquires Sherrington Pharmaceuticals, Inc., or Sherrington, and advances its pain drug into clinical trials, (iii) continues to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) acquires Concortis Biosystems, Corp., or Concortis, and (v) expands its corporate infrastructure, including the costs associated with being a public company. See Note 7.

In September 2013, the Company entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, which was funded at closing. Contemporaneously with such closing, the Company repaid its then outstanding equipment loan balance of $762,361. In October 2013, the Company: (i) closed an underwritten public offering of 4,772,500 shares of its common stock, including the Underwriters exercise of an over-allotment of 622,500 shares of common stock, at $7.25 per share and total gross proceeds of $34.6 million, and (ii) issued an aggregate $1,850,000 principal amount of Convertible Promissory Notes (the Notes) that bear interest at 7% per annum. Such Notes and related accrued interest automatically converted into 256,119 shares of common stock at $7.25 per share effective in October 2013. Management believes the Company has the ability to meet all obligations due over the course of the next twelve months. See Note 7.

The Company plans to continue to fund its losses from operations 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 October 2013 underwritten offering, the Company has the ability to offer up to $65.4 million of additional securities. Pursuant to the Shelf Registration Statement, the Company may offer such securities from time to time and through one or more methods of distribution, subject to market conditions and the Company s 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, 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. In addition, if the Company does not meet its payment obligations to third parties as they come due, it may be subject to litigation claims. Even if the Company is 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 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 ratios that may restrict the Company s ability to operate its business.

Principles of Consolidation

The financial statements also include the accounts of the Company s wholly-owned subsidiaries, IgDraSol, Sorrento Therapeutics, Inc. Hong Kong Limited, or Sorrento Hong Kong. Sorrento Hong Kong had no operating activity through September 30, 2013. All inter-company balances and transactions have been eliminated in consolidation.

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. Such adjustments could include, for example, appropriate estimates for Company bonus plans normally determined or settled at year-end.

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.

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Fair Value of Financial Instruments

The Company s financial instruments consist of cash and cash equivalents, grants receivable, prepaid expenses and other assets, accounts payable and accrued expenses. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. As of September 30, 2013 and December 31, 2012, the carrying amount of cash and cash equivalents, grants receivable, prepaid expenses and other assets, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

Grants Receivable

Grants receivable at September 30, 2013 and December 31, 2012 represent amounts due under federal contracts with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health (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.

Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets. Such lives vary from three to five years. Leasehold improvements are amortized over the lesser of the life of the lease or the life of the asset.

Intangibles

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. The Company had no patent rights as of December 31, 2012. Amortization expense for the three and nine months ended September 30, 2013 was $1,250 and $2,500, respectively, which has been included in intangibles amortization.

License rights are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, determined to be approximately fifteen years from the date of acquisition of the rights in September 2013. The Company had no licenses rights as of December 31, 2012. Amortization expense for the three and nine months ended September 30, 2013 was $110,839, which has been included in intangibles amortization.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets with definite lives, such as property and equipment, 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, 2013.

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 no uncertain tax positions.

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. The Company evaluates the recoverability of the

deferred tax assets annually.

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Revenue Recognition

The Company s revenues are generated from the NIH and U.S. Treasury grant awards and a feasibility study agreement, or the Collaboration Agreement, that the Company entered into with a third party in July 2010. The revenue from the NIH and U.S. Treasury grant awards are 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.

The revenue from the Collaboration Agreement is derived from the completion of certain development services and the reimbursement of certain development costs incurred to provide such development services. Revenue from upfront, nonrefundable service fees are recognized when earned, as evidenced by written acknowledgement from the collaborator, or other persuasive evidence that all service deliverables have been achieved, provided that the service deliverables are substantive and their achievability was not reasonably assured at the inception of the Collaboration Agreement. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue.

Research and Development Costs and Collaborations

Research and development costs are charged to expense as incurred. Such costs primarily consist of discovery research, pre-clinical activities, manufacture of drug supply, lab supplies, contract and acquired services, stock-based compensation expense, salaries and related benefits, depreciation and allocated and direct facility expenses.

The Company evaluates its collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments to collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for these payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due to collaborative partners related to development activities are reflected as a research and development expense.

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 payments to acquire a new drug compound, as well as future milestone payments, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use.

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 measured at the grant date, based on the calculated fair value of the award, 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 granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at estimated fair value as they vest.

Net Loss per Share

Net loss per share is presented as both basic and diluted net loss per share. Basic net loss per share excludes any dilutive effects of options, shares subject to repurchase and warrants. Diluted net loss per share includes the impact of potentially dilutive securities. No dilutive effect was calculated for the three or nine months ended September 30, 2013 and 2012 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive. The Company had outstanding common share equivalents of 551,850 and 460,668 at September 30, 2013 and 2012, respectively. The Company excludes the potential issuance of common shares contingently issuable to the Lees or IgDraSol as there is no guarantee that such shares will be issued in the future. See Notes 2 and 3.

New Accounting Standards

In July 2012, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update, or ASU, 2012-02, Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (the revised standard). The objective of this ASU is to simplify how entities test indefinite-lived intangible assets other than goodwill for impairment. The amendments in the ASU provide the option to first assess qualitative factors to determine whether, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) the asset is impaired and it is necessary to calculate the fair

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value of the asset in order to compare that amount to the carrying value to determine the amount of the impairment, if any. If an entity believes, as a result of its qualitative assessment, that it is not more-likely-than-not (a likelihood of more than 50%) that the fair value of an asset is less than its carrying amount, no further testing is required. The revised standard includes examples of events and circumstances that might indicate that the indefinite-lived intangible asset is impaired. The approach in the ASU is similar to the guidance for testing goodwill for impairment contained in ASU 2011-08, intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment. The revised standard, which may be adopted early, is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and does not change existing guidance on when to test indefinite-lived intangible assets for impairment. The adoption of the provisions of this guidance is not expected to have a material impact on the Company s consolidated results of operations, cash flows, and financial position.

2. Significant Agreements and Contracts

License Agreement with OPKO Health, Inc.

In June 2009, the Company entered into a limited license agreement, or the OPKO License, with OPKO Health, Inc., or OPKO, pursuant to which the Company granted OPKO an exclusive, royalty-free, worldwide license under all U.S. and foreign patents and patent applications owned or controlled by the Company or any of its affiliates, or the STI Patents, to: (i) develop, manufacture, use, market, sell, offer to sell, import and export certain products related to the development, manufacture, marketing and sale of drugs for ophthalmological indications, or the OPKO Field, and (ii) use and screen any population of distinct molecules covered by any claim of the STI Patents or which is derived by use of any process or method covered by any claim of the STI Patents to identify, select and commercialize certain products within the OPKO Field. Subject to certain limitations, OPKO will have the right to sublicense the foregoing rights granted under the OPKO License. Additionally, pursuant to the OPKO License, OPKO has granted the Company an exclusive, royalty-free, worldwide license to any patent or patent application owned or controlled by OPKO or any of its affiliates to develop, use, make, market, sell and distribute certain products in any field of use, other than the OPKO Field, or the OPKO Patents.

The Company has retained all rights to the STI Patents outside of the OPKO Field and has agreed not to practice the OPKO Patents or the STI Patents outside the STI current field of use. Unless otherwise terminated in accordance with its terms, the License Agreement will expire upon the expiration of the last to expire patent within the STI Patents and OPKO Patents on a country-by-country basis.

License Agreement with The Scripps Research Institute

In January 2010, the Company entered into a license agreement, or the TSRI License, with The Scripps Research Institute, or TSRI. Under the TSRI License, TSRI granted the Company an exclusive, worldwide license to certain TSRI patent rights and materials based on quorum sensing for the prevention and treatment of Staphylococcus aureus (Staph) infections, including Methicillin-resistant Staph. In consideration for the license, the Company: (i) issued TSRI a warrant for the purchase of common stock, (ii) agreed to pay TSRI a certain annual royalty commencing in the first year after certain patent filing milestones are achieved, (iii) agreed to pay a royalty on any sales of licensed products by the Company or its affiliates and a royalty for any revenues generated by the Company through its sublicense of patent rights and materials licensed from TSRI under the TSRI License. The TSRI License requires the Company to indemnify TSRI for certain breaches of the agreement and other matters customary for license agreements. The parties may terminate the TSRI License at any time by mutual agreement. In addition, the Company may terminate the TSRI License by giving 60 days notice to TSRI and TSRI may terminate the TSRI License immediately in the event of certain breaches of the agreement by the Company or upon the Company s failure to undertake certain activities in furtherance of commercial development goals. Unless terminated earlier by either or both parties, the term of the TSRI License will continue until the final expiration of all claims covered by the patent rights licensed under the agreement. For the three months ended September 30, 2013 and 2012 and for the period from inception (January 25, 2006) (Inception) through September 30, 2013, the Company recorded $13,418, $5,293 and $147,570 in patent prosecution and maintenance costs associated with the TSRI License, respectively. For the nine months ended September 30, 2013 and 2012, the Company recorded $20,225 and $27,861 in patent prosecution and maintenance costs associated with the TSRI License, respectively. All such costs have been included in general and administrative expenses.

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License Agreement with B.G. Negev Technologies and Applications Ltd.

In July 2013, the Company entered into an exclusive option agreement with B.G. Negev Technologies and Applications Ltd. (BGN). Pursuant to the terms of the option agreement, BGN granted the Company an option to receive an exclusive sub-licensable worldwide license in and to certain licensed patent rights to develop and commercialize the licensed products. Licensed patent rights refers to any rights arising out of or resulting from any patent application filed by the Company for certain BGN technology relating to a group of defined fully human antibodies that bind to a Hep. C protease enzyme.

NIH Grants

In May 2010, the NIAID awarded the Company an Advanced Technology Small Business Technology Transfer Research grant to support the Company s program to generate and develop novel antibody therapeutics and vaccines to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant award. The project period for the Staph Grant award covers a two-year period which commenced in June 2010, with a potential award of $300,000 per year. As of December 31, 2012, the entire Phase 1 grant of $600,000 had been awarded and recognized as revenue. The Company records revenue associated with the grant as the related costs and expenses are incurred. During the three and nine months ended September 30, 2012, and for the period from Inception through September 30, 2013, the Company recorded $0, $119,379 and $600,000 of revenue associated with the Staph Grant award, respectively.

In July 2011, the NIAID awarded the Company a second Advanced Technology Small Business Technology Transfer Research grant, with an initial award of $300,000, to support the Company s program to generate and develop antibody therapeutics and vaccines to combat C. difficile infections, or the C. difficile Grant award. The project period for the C. difficile Grant award covers a two-year period which commenced in June 2011, and as of September 30, 2012, the entire Phase 1 grant of $600,000 had been awarded. During the three months ended September 30, 2013 and 2012, and for the period from Inception through September 30, 2013, the Company recorded $0, $94,707 and $592,717 of revenue associated with the C. difficile Grant award, respectively. During the nine months ended September 30, 2013 and 2012, the Company recorded $143,940 and $265,811 of revenue associated with the C. difficile Grant award, respectively.

In June 2012, the NIAID awarded the Company a third Advanced Technology Small Business Technology Transfer Research grant, with an initial award of $300,000, 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 potential annual award of $300,000 per year. During the three months ended September 30, 2013 and 2012, and for the period from Inception through September 30, 2013, the Company recorded $83,791, $39,799 and $344,328, respectively, of revenue associated with the Staph Grant II award. During the nine months ended September 30, 2013 and 2012, the Company recorded $215,512 and $39,799 of revenue associated with the Staph Grant II award, respectively.

Collaboration Agreement

In July 2010, the Company entered into the Collaboration Agreement with a third party. Under the terms of the Collaboration Agreement, the Company provided certain antibody screening services for an upfront cash fee of $200,000 and was reimbursed for certain costs and expenses associated with providing the services, or the Development Costs. The upfront fee and reimbursable Development Costs were accounted for as separate units of accounting. The Company recorded the gross amount of the reimbursable Development Costs as revenue and the costs associated with these reimbursements are reflected as a component of research and development expense.

Any amounts received by the Company pursuant to the Collaboration Agreement prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue. All agreed upon services under the Collaboration Agreement were delivered in March 2011. For the period from Inception through September 30, 2013, the Company recognized $223,453 in revenue.

U.S. Treasury Grants

During 2010, the U.S. Treasury awarded the Company grants totaling $394,480 for investments in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The proceeds from this grant are classified in Revenues Grant for the period from Inception through September 30, 2013.

Assignment Agreement

In January 2013, the Company entered into the assignment agreement, pursuant to which the Lees agreed to assign to the Company their right, title and interest throughout the world in and to certain inventions and patents that provide for the production of recombinant intravenous

immunoglobulin. As consideration for the assignment by the Lees under the assignment agreement, the

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Company: (i) issued the Lees 10,000 shares of the Company s common stock upon execution of the assignment agreement, (ii) paid the Lees $50,000 in five monthly installments of $10,000 beginning on February 1, 2013, and (iii) agreed to issue the Lees up to 80,000 shares of the Company s common stock based upon the achievement of certain milestone events described in the assignment agreement. Unless otherwise terminated in accordance with its terms, the assignment agreement will expire upon the expiration of the last to expire patent within the assigned patent rights.

3. IgDraSol Transactions and Acquisition

On March 7, 2013, the Company entered into an exclusive option agreement with IgDraSol, a private company focused on the development of oncologic agents for the treatment of MBC, NSCLC, and other cancers. IgDraSol granted the Company an irrevocable option to acquire IgDraSol by means of an agreement and plan of merger, and was paid a non-refundable lump sum payment of $200,000 in April 2013. Such payment was capitalized and amortized in full over the life of the option period as intangibles amortization as of September 30, 2013.

The Company entered into an initial services agreement dated March 7, 2013 with IgDraSol, wherein IgDraSol provided certain product development and technology services related to antibody-based nanotherapeutics. In March 2013, IgDraSol was paid a non-refundable payment of $1,000,000 and the related services were completed prior to May 31, 2013. In addition, the Company entered into an asset purchase agreement with IgDraSol whereby it agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies for a purchase price of $1,210,000. The purchase price was paid in April 2013 and was recognized as acquired in-process research and development expense. Also in April 2013, the Company entered into a development services agreement with IgDraSol related to the development of Tocosol® and related technologies. For the three and nine months ended September 30, 2013, the Company recorded $875,133 and $1,721,193, respectively, of operating expenses associated with the development services agreement.

On September 9, 2013, the Company exercised its option to acquire IgDraSol whereby IgDraSol became a wholly-owned subsidiary. Pursuant to the merger agreement, the Company issued 3,006,641 shares of common stock to IgDraSol stockholders and paid $0.4 million in cash. Upon the later achievement of a specified regulatory milestone, the Company will issue an additional 1,306,272 shares of common stock to former IgDraSol stockholders.

The following tables summarize the consideration transferred to acquire IgDraSol and the amounts of identified assets acquired and liabilities assumed at the acquisition date.

The purchase price is summarized as follows:

		(in thousands)
Cash buyout of certain holders of IgDraSol common stock options and warrants	$	356.1
Market value of shares of Sorrento common stock issued in exchange for IgDraSol common stock		27,811.4
Transaction fees, including separation and bonus payments of $771,000 made to IgDraSol employees		937.8
Total purchase price	$	29,105.3

The purchase price has been allocated based on the fair value of assets acquired and liabilities assumed ($ in thousands):

Assets acquired:		
Cash	$	125.8
Prepaid expenses & other		44.9
PP&E		120.9
Intangible license rights		29,105.3

Total assets	29,396.9
Liabilities assumed:	
Accounts payable	167.7
Accrued expenses	123.9
Total liabilities	291.6
Total purchase price	$ 29,105.3

The intangible license rights will be amortized through fiscal 2028 at an annual rate of $1,900,093.

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4. Debt

Equipment Loan and Security Agreement

In February 2013, the Company entered into an equipment loan and security agreement with a bank pursuant to which the lender provided the Company a loan in the principal amount of $875,888 to finance certain equipment. Interest accrues on the outstanding advance at the fixed rate of 5.15%. The Company granted the lender a security interest in any equipment that is financed under the equipment loan agreement. In September 2013, the equipment loan was paid in full, the Company had no further obligations thereunder, and the bank released its security interest in such assets.

Loan and Security Agreement

In September 2013, the Company entered into a $5,000,000 loan and security agreement with two banks pursuant to which the lenders provided the Company a term loan, or the Term Loan, which was funded at closing. The interest rate on the Term Loan is 7.95% per annum. The Company will make interest only payments on the outstanding amount of the loan on a monthly basis until November 1, 2014, after which equal monthly payments of principal and interest are due. The maturity date of the Term Loan is April 15, 2017. The Term Loan is secured by a security interest in all of the Company s assets except intellectual property. The Company s intellectual property is subject to a negative pledge. In connection with the Term Loan, 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 $214,680, was recorded as debt discount and additional paid-in capital in the consolidated balance sheet as of September 30, 2013.

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 a final fee of $200,000.

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.

Future annual principal payments under the loan agreement, as of September 30, 2013, are as follows:

2014	$ 303,406
2015	1,907,040
2016	2,064,298
2017	725,256
Debt discount	(214,680)
Long-term debt	$ 4,785,320

5. Stockholders Equity

Common Stock and Related Party Transaction

In December 2011, the Company entered into a Stock Purchase Agreement, or the Stock Purchase Agreement, and issued 500,000 shares of common stock in a private placement transaction at $4.00 per share, for aggregate gross proceeds of $2,000,000. In May 2012, the Company entered into an Amended and Restated Stock Purchase Agreement, and issued 1,500,000 shares of common stock in a private placement transaction at $4.00 per share, for aggregate gross proceeds of $6,000,000. Two hundred and fifty thousand of the shares were purchased by an investor, Hongye SD Group, LLC, of which Dr. Henry Ji, the Company s Chief Executive Officer and President, is a managing director.

In January 2013, the Company entered into the assignment agreement and issued 10,000 shares of common stock valued at $40,000.

In March 2013, the Company entered into a Stock Purchase Agreement and issued 1,426,406 shares of common stock, in a private placement transaction, at $4.50 per share for aggregate gross proceeds of $6,418,495.

In April 2013, Company s stockholders approved, among other items, three amendments to the Company s Certificate of Incorporation, as follows: (i) increased the number of shares of common stock authorized to be issued by the Company from

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500,000,000 to 750,000,000, (ii) authorized the Company s Board of Directors, or the Board, to effect a reverse stock split of the Company s common stock by a ratio of not less than 1-for-2 and not more than 1-for-150, with the Board having the discretion as to whether or not the reverse split is to be effected at any time prior to April 26, 2014, and (iii) authorized the Board, in the event a reverse stock split is approved, in its discretion, to reduce the number of shares of common stock authorized to be issued by the Company in proportion to the percentage decrease in the number of outstanding shares of common stock resulting from the reverse split (or a lesser decrease in authorized shares of common stock as determined by the Board in its discretion). See Note 1.

Stock Incentive Plans

2009 Equity Incentive Plan

In February 2009, prior to the Merger, the Company s Board of Directors approved the 2009 Equity Incentive Plan, or the EIP, under which 400,000 shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company. In March 2009, the Company issued 296,155 restricted common stock awards to certain consultants for aggregate gross proceeds of $291, of which the Company repurchased 44,166 unvested shares of restricted common stock for $43 in January 2011. The restricted shares vested monthly over four years and all remaining shares were fully vested as of September 30, 2013. No further shares are available for grant under the EIP.

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. Such options are exercisable on the two year anniversary of the grant date and are generally exercisable for up to 10 years from the grant date. No further shares may be granted under this plan and, as of September 30, 2013, 3,200 options were outstanding.

2009 Stock Incentive Plan

In October 2009, the Company s stockholders approved the 2009 Stock Incentive Plan. In April 2013, 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 stock authorized to be issued pursuant to the Stock Plan to 1,360,000. Such shares of the Company s common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. In addition, this amount will be automatically increased annually on the first day of each fiscal year by the lesser of: (i) 1% of the aggregate number of shares of the Company s common stock outstanding on the last day of the immediately preceding fiscal year, (ii) 200,000 shares, or (iii) an amount approved by the administrator of the Stock Plan. 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 each anniversary of the original vesting date over four years. The vesting schedules for grants to non-employee directors and consultants will be determined by the Company s Compensation Committee. Stock options are generally not exercisable prior to the applicable vesting date, unless otherwise accelerated under the terms of the applicable stock plan agreement. Unvested shares of the Company s common stock issued in connection with an early exercise however, may be repurchased by the Company upon termination of the optionee s service with the Company.

During the nine months ended September 30, 2013 and 2012, the Company s Board of Directors awarded 110,200 and 325,200 options to certain employees and consultants and 833,400 and 147,800 shares were available for grant under the Stock Plan, respectively.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock based compensation expense is recognized over the vesting period using the straight-line method. The fair value of employee stock options was estimated at the grant date using the following assumptions:

	Nine months ended September 30,	
	2013	2012
Dividend yield		
Volatility	109%	102%
Risk-free interest rate	1.19%	0.71% - 1.11%

Expected life of options	6.1 years	5.6 years

The weighted average grant date fair value per share of employee stock options granted during the nine months ended September 30, 2013 and 2012 was $4.78 and $3.25, respectively.

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The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. Due to the Company s limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the United States 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 $157,853, $20,685 and $873,140 for the three months ended September 30, 2013 and 2012 and for the period from Inception through September 30, 2013, respectively. The total employee stock-based compensation recorded as operating expenses was $454,324 and $75,350 for the nine months ended September 30, 2013 and 2012, respectively.

As of September 30, 2013, unrecognized compensation cost related to the options was $1,654,334 which will be recognized over 2.9 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 applicable 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 $34,254, $66,130 and $1,215,270 for the three months ended September 30, 2013 and 2012 and for the period from Inception through September 30, 2013, respectively. Stock-based compensation expense related to non-employee consultants recorded as operating expenses was $167,447 and $214,722 for the nine months ended September 30, 2013 and 2012, respectively.

6. Income Taxes

The Company maintains deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, research credits and capitalized research and development. The net deferred tax asset has been fully offset by a valuation allowance because of the Company s history of losses. Utilization of operating losses and credits may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

7. Subsequent Events

Agreement and Plan of Merger Sherrington

On October 9, 2013, the Company and SP Merger Sub, Inc., a wholly owned subsidiary of the Company, Sherrington Pharmaceuticals, Inc. and the stockholders of Sherrington (the Sherrington Holders) entered into an Agreement and Plan of Merger and Reorganization (the Agreement) pursuant to which the Company issued an aggregate of 200,000 shares of its common stock to the Sherrington Holders (the Merger Shares) and SP Merger Sub was merged into Sherrington (the Merger). Pursuant to the Agreement, 29,350 of the Merger Shares are being held in escrow for any potential indemnification claims. The Company filed a resale registration statement on Form S-3 with the Securities and Exchange Commission on October 31, 2013 to register the Merger Shares.

Underwritten Public Offering and Nasdaq Uplisting

Underwritten Public Offering of Common Stock

On October 30, 2013, the Company closed an underwritten public offering of 4,150,000 shares of common stock, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by the Company. The common stock began trading on The NASDAQ Capital Market on October 25, 2013 under the symbol SRNE .

Purchase Warrants

Concurrent with the offering, the Company agreed to issue and sell to the underwriters a warrant (Underwriters Warrant) for the purchase of an aggregate of 182,600 shares of Common Stock, representing 4.4% of the Firm Shares, for an aggregate purchase price of $100. The Underwriters Warrant agreement is exercisable, in whole or in part, commencing on a date which is one (1) year after the effective date of the Registration Statement and expiring on the five-year anniversary of the effective date of the Registration Statement at an initial exercise price per share of Common Stock of $9.0625, which is equal to 125% of the initial public offering price of the Firm Shares.

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Convertible Promissory Notes

In October 2013, the Company issued an aggregate $1,850,000 principal amount of Notes that bear interest at 7% per annum. Concurrently with the closing of the public offering, such Notes and related accrued interest automatically converted into 256,119 shares of common stock.

Agreement of Merger Concortis

On November 11, 2013, the Company and Catalyst Merger Sub, Inc., a wholly owned subsidiary of the Company, Concortis Biosystems, Corp. (Concortis) and Zhenwei Miao and Gang Chen entered into an Agreement of Merger pursuant to which, at the effective time of the merger, the Company will issue an aggregate of 1,331,978 shares of its common stock to the shareholders of Concortis (the Concortis Merger Shares) and Catalyst Merger Sub will merge into Concortis (the Concortis Merger). Pursuant to the merger agreement, 15% of the Concortis Merger Shares will be held by the Company for any potential indemnification claims.

In connection with the merger, the Company agreed to appoint Dr. Zhenwei (David) Miao, the former President and Chief Scientific Officer of Concortis, as its Chief Technical Officer. In addition, Dr. Miao and certain other employees of Concortis are to receive annual supplemental cash bonus payments totaling $1,000,000 on December 31 of each of the years ending 2013, 2014, 2015, and 2016.

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 United States, Europe and additional international markets. Our primary therapeutic focus is oncology but we are also developing therapeutic products for other indications, including inflammation, metabolic disorders, and infectious diseases.

Our proprietary G-MAB® fully-human antibody library platform was designed to facilitate the rapid identification and isolation of highly specific antibody therapeutic product candidates that bind to disease targets appropriate for antibody therapy. Our objective is to leverage our library to develop both First-in-Class, or FIC, and/or Best-in-Class, or BIC, antibody drug candidates that we expect will possess greater efficacy and fewer side effects as compared to existing drugs. Although we intend to retain ownership and control of some product candidates by advancing them further into preclinical development, we will also consider partnerships with pharmaceutical or biopharmaceutical organizations, with the appropriate experience and expertise, in order to balance the risks associated with drug discovery and development and maximize our stockholders returns. Our partnering objectives include generating revenue through license fees, milestone related development fees and royalties by licensing rights to our development candidates.

Our goal is to deliver innovative, highly effective and safe treatment options to patients throughout the world. By working closely with scientists, doctors, patient organizations and other health care specialists, we are committed to improving the lives of patients and assisting their caregivers in the fight against cancer, inflammatory and autoimmune diseases and other unmet medical needs.

Recent Developments

IgDraSol Transactions, Cynviloq and Merger

On July 29, 2013, IgDraSol, Inc., or IgDraSol, received official meeting minutes from an End-of-Phase 2 meeting held on July 23, 2013 for Cynviloq (or IG-001) with the U.S. Food and Drug Administration, or FDA. Cynviloq (paclitaxel polymeric micelle) is initially under development for the treatment of metastatic breast cancer, or MBC, and non-small cell lung cancer, or NSCLC, in the U.S. The FDA Division of Oncology Products 1 agreed that the data available from: (i) the postmarketing surveillance studies conducted in ex-U.S. territories for MBC and NSCLC, (ii) Phase 1-3 studies for MBC, and (iii) Phase 1-2 studies in NSCLC,

Ovarian, Bladder, and Pancreatic cancers are sufficient to support pursuing the 505(b)(2) Bioequivalence (BE) regulatory submission pathway approach using Abraxane® and Taxol® as the Reference Listed Drugs. Abraxane® is an albumin-bound paclitaxel (nab-paclitaxel) product approved for MBC, NSCLC and pancreatic cancer indications. Taxol® is a cremophor-based paclitaxel product approved for these indications as well as other cancer indications. IgDraSol anticipates filing its BE protocol with the FDA by the end of 2013. Sufficiency of the data for approval will be a review issue after a New Drug Application, or NDA, filing.

On September 9, 2013, we exercised our previously disclosed option to acquire IgDraSol and pursuant to an agreement and plan of merger dated as of such date, we issued 3,006,641 shares of our common stock, to the IgDraSol stockholders. Upon the achievement of a certain regulatory milestone, we will be required to issue an additional 1,306,272 shares of common stock to former IgDraSol stockholders.

In connection with the merger, we appointed (i) Dr. Vuong Trieu, the former Chief Executive Officer of IgDraSol, as our Chief Scientific Officer and (ii) George Uy, the former Chief Commercial Officer of IgDraSol, as our Chief Commercial Officer. In addition, Dr. Trieu and Mr. Jaisim Shah were appointed to our board of directors.

Cynviloq is a micellar diblock copolymeric paclitaxel formulation drug product that is currently approved and marketed in several countries, including South Korea for MBC and NSCLC under the trade name Genexol-PM®. IgDraSol obtained exclusive distribution rights for Cynviloq in the U.S. and 27 countries of the European Union, or EU, from Samyang Biopharmaceuticals Corporation, a South Korean corporation.

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We entered into an initial services agreement dated March 7, 2013 with IgDraSol, wherein IgDraSol has provided certain product development and technology services related to antibody-based nanotherapeutics. In March 2013, IgDraSol was paid a non-refundable payment of $1,000,000 and the related services were completed prior to May 31, 2013. There are no further obligations under the initial services agreement.

In addition, we entered into an asset purchase agreement with IgDraSol whereby we agreed to purchase all documentation, equipment, information and other know-how related to micellar nanoparticle technology encompassing Tocosol® and related technologies for a purchase price of $1,210,000, which was paid in April 2013, which was recognized as in-process research and development expense. Also in April 2013, we entered into a development services agreement with IgDraSol related to the development of Tocosol® and related technologies. We will pay IgDraSol up to $3,000,000 for services provided.

Agreement and Plan of Merger with Sherrington

On October 9, 2013, the Company and SP Merger Sub, Inc., a wholly owned subsidiary of the Company, Sherrington Pharmaceuticals, Inc. (Sherrington) and the stockholders of Sherrington (the Sherrington Holders) entered into an Agreement and Plan of Merger and Reorganization (the Agreement) pursuant to which the Company issued an aggregate of 200,000 shares of its common stock to the Sherrington Holders (the Merger Shares) and SP Merger Sub was merged into Sherrington (the Merger). Pursuant to the Agreement, 29,350 of the Merger Shares are being held in escrow for any potential indemnification claims. The Company filed a resale registration statement on Form S-3 with the Securities and Exchange Commission on October 31, 2013 to register the Merger Shares.

Underwritten Public Offering and Nasdaq Uplisting

In October 2013, the Company closed an underwritten public offering of 4,150,000 shares, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by us. The common stock began trading on The NASDAQ Capital Market on October 25, 2013 under the symbol SRNE .

Convertible Promissory Notes

In October 2013, the Company issued an aggregate $1,850,000 principal amount of Notes that bear interest at 7% per annum. Concurrently with the closing of the public offering, such Notes and related accrued interest automatically converted into 256,119 shares of common stock.

Agreement of Merger Concortis

On November 11, 2013, the Company and Catalyst Merger Sub, Inc., a wholly owned subsidiary of the Company, Concortis Biosystems, Corp. (Concortis) and Dr. Zhenwei (David) Miao and Gang Chen entered into an Agreement of Merger pursuant to which, at the effective time of the merger, the Company will issue an aggregate of 1,331,978 shares of its common stock to the shareholders of Concortis (the Concortis Merger Shares), and Catalyst Merger Sub will merge into Concortis (the Concortis Merger). Pursuant to the merger agreement, 15% of the Concortis Merger Shares will be held by the Company for any potential indemnification claims.

In connection with the merger, the Company agreed to appoint Dr. Miao, the former President and Chief Scientific Officer of Concortis, as its Chief Technical Officer. In addition, Dr. Miao and certain other employees of Concortis are to receive annual supplemental cash bonus payments totaling $1,000,000 on December 31 of each of the years ending 2013, 2014, 2015, and 2016.

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 consolidated 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, 2013, there were no significant changes to the items that we disclosed as our critical accounting policies and estimates in Note 2 to our financial statements for the year ended December 31, 2012 contained in our 2012 Form 10-K, as filed with the SEC.

Results of Operations

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

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Three Months Ended September 30, 2013 Compared to the Three Months Ended September 30, 2012

Revenues. Revenues were $83,791 for the three months ended September 30, 2013, as compared to $134,506 for the three months ended September 30, 2012. The decrease is due to lower grant revenue of $50,715 due to decreased grant activities under one active grant award during 2013 as compared to two active grants during 2012.

In May 2010, we were awarded an Advanced Technology Small Business Technology Transfer Research grant to support our program to generate and develop novel antibody therapeutics and vaccines to combat Staph infections, including Methicillin-resistant Staph, or the Staph Grant award. The project period for this grant covered a two-year period which commenced in June 2010, and as of June 30, 2012, the entire Phase 1 grant of $600,000 had been awarded and recognized in grant revenues.

In July 2011, we were awarded a second Advanced Technology Small Business Technology Transfer Research grant to support our program to generate and develop antibody therapeutics and vaccines to combat C. difficile infections, or the C. difficile Grant award. The project period for the C. difficile Grant award covers a two-year period which commenced in June 2011, and as of June 30, 2013, the entire Phase 1 grant of $600,000 had been awarded. From July 2011 through September 30, 2013, $592,717 of the C. difficile Grant award had been recorded in grant revenues.

In June 2012, we were awarded a third Advanced Technology Small Business Technology Transfer Research grant, with an initial award of $300,000, 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 potential annual award of $300,000 per year. From June 2012 through September 30, 2013, $344,328 of the Staph Grant II award had been recorded in grant revenues.

We had no other revenue during the three months ended September 30, 2013 and 2012. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the unpredictability of the timing and amount of grant awards, research and development reimbursements and other payments received under our strategic collaborations.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2013 and 2012 were $2,082,252 and $950,823, respectively. Research and development expenses include the costs to identify, isolate and advance human antibody drug candidates derived from our libraries, preclinical testing expenses, costs incurred under the IgDraSol initial and development services agreements, and the expenses associated with fulfilling our development obligations related to the Staph and C. difficile Grant awards, collectively the NIH Grants. Such expenses consist primarily of salaries and personnel -related expenses, stock-based compensation expense, laboratory supplies, consulting costs and other expenses. The increase of $1,131,429 is primarily attributable to costs incurred under the initial and development services agreements with IgDraSol, as well as higher salary and lab supply costs incurred in connection with our expanded research and development activities. We expect research and development expenses to increase in absolute dollars as we: (i) advance our Cynviloq™ asset into a registration trial (a single bioequivalence study) and pursue other potential indications, including expenses incurred under agreements with CROs and investigative sites that conduct their clinical trials, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (ii) acquire Sherrington and advance its pain drug into clinical trials, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) acquire Concortis, and (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs.

We evaluate our collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments to our collaborative partners are not within the scope of other authoritative accounting literature, the statement of operations classification for these payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due to our collaborative partners related to development activities are reflected as a research and development expense.

Acquired In-Process Research and Development Expenses. Acquired research and development expenses for the three months ended September 30, 2013 and 2012 was $0.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2013 and 2012 were $1,114,621 and $427,030, respectively. General and administrative expenses consist primarily of costs incurred under the IgDraSol initial and development services agreements, salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation, professional fees, infrastructure expenses, legal and accounting, and other general corporate expenses. The increase of $687,591 is primarily attributable to increases in costs incurred under the initial and development services agreement with IgDraSol, stock-based compensation, salaries and consulting expenses with the addition of our full time Chief Financial Officer and part-time Chief Business Officer in

the second half of 2012, and higher legal and compliance costs associated with our public reporting obligations. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, compliance with our public reporting obligations, (ii) assume all of the costs associated with the merger with IgDraSol and IgDraSol s ongoing operating expenses, and (iii) incur costs related to the Sherrington and Concortis mergers and integrate their operations.

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Intangibles Amortization. Intangibles amortization for the three months ended September 30, 2013 and 2012 was $193,755 and $0, respectively. Our amortization expense is higher due to the IgDraSol option agreement and acquisition in September 2013 and the entering into of the assignment agreement in January 2013.

Interest Income and Interest Expense. Interest income and interest expense for the three months ended September 30, 2013 and 2012 was nominal. We expect interest expense to increase in absolute dollars as we incur incremental costs associated with the loan and security agreement entered into in September 2013.

Net Loss. Net loss for the three months ended September 30, 2013 and 2012 was $3,356,445 and $1,241,229, respectively. The increase in net loss is mainly attributable to the expanded general and administrative and research and development activities, including the costs associated with the IgDraSol Transactions and the IgDraSol and Sherrington mergers.

Nine Months Ended September 30, 2013 Compared to the Nine Months Ended 30, 2012

Revenues. Revenues were $359,451 for the nine months ended September 30, 2013, as compared to $461,790 for the nine months ended September 30, 2012. The decrease is due to lower grant revenue of $102,339 due to decreased grant activities under two grant awards during 2013 as compared to three active grants during 2012.

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of grant awards and when the related costs and expenses are incurred, and timing of any other payments received under our strategic collaborations.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2013 and 2012 were $5,621,969 and $2,667,347, respectively. Research and development expenses include the costs to identify, isolate and advance human antibody drug candidates derived from our libraries, preclinical testing expenses, costs incurred under the IgDraSol initial and development services agreements, and the expenses associated with fulfilling our development obligations related to the Staph and C. difficile Grant awards, collectively the NIH Grants. Such expenses consist primarily of salaries and personnel-related expenses, stock-based compensation expense, laboratory supplies, consulting costs and other expenses. The increase of $2,954,622 is attributable to costs incurred under the initial and development services agreements with IgDraSol, as well as higher salary and lab supply costs incurred in connection with our expanded research and development activities. We expect research and development expenses to increase in absolute dollars as we: (i) advance our Cynviloq™ asset into a registration trial (a single bioequivalence study) and pursue other potential indications, including expenses incurred under agreements with CROs and investigative sites that conduct their clinical trials, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (ii) acquire Sherrington and advance its pain drug into clinical trials, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) acquire Concortis, and (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs.

Acquired In-Process Research and Development Expenses. Acquired research and development expenses for the nine months ended September 30, 2013 and 2012 was $1,210,000 and $0, respectively. Acquired research and development expenses include the costs of acquiring the Tocosol® and related technologies in April 2013.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2013 and 2012 were $3,752,233 and $890,262, respectively. General and administrative expenses consist primarily of costs incurred under the IgDraSol initial and development services agreements, salaries and personnel related expenses for executive, finance and administrative personnel, stock-based compensation, professional fees, infrastructure expenses, legal and accounting, and other general corporate expenses. The increase of $2,861,971 is primarily attributable to increases in costs incurred under the initial and development services agreement with IgDraSol, stock-based compensation, salaries and consulting expenses with the addition of our full time Chief Financial Officer and part-time Chief Business Officer in the second half of 2012, and higher legal and compliance costs associated with our public reporting obligations. We expect general and administrative expenses to increase in absolute dollars as we: (i) incur incremental expenses associated with expanded operations and development efforts, compliance with our public reporting obligations, (ii) assume all of the costs associated with the merger with IgDraSol and IgDraSol s ongoing operating expenses, and (iii) incur costs related to the Sherrington and Concortis mergers and integrate their operations.

Intangibles Amortization. Intangibles amortization for the nine months ended September 30, 2013 and 2012 was $313,339 and $0, respectively. Our amortization expense is higher due to the IgDraSol option agreement and acquisition in September 2013 and the entering into of the assignment agreement in January 2013.

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Interest Income and Interest Expense. Interest income and interest expense for the nine months ended September 30, 2013 and 2012 were nominal. We expect interest expense to increase in absolute dollars as we incur incremental costs associated with the loan and security agreement entered into in September 2013.

Net Loss. Net loss for the nine months ended September 30, 2013 and 2012 was $10,615,396 and $3,090,473, respectively. The increase in net loss is mainly attributable to the expanded general and administrative and research and development activities, including the costs associated with the IgDraSol Transactions. The increase in net loss is mainly attributable to the expanded general and administrative and research and development activities, including the costs associated with the IgDraSol Transactions and the IgDraSol and Sherrington mergers.

Liquidity and Capital Resources

As of September 30, 2013, we had $6,429,712 in cash and cash equivalents, attributable primarily to the closing of our private placement of our common stock for aggregate gross proceeds of $6,418,495 in March 2013, as well as the $5,000,000 loan and security agreement with the banks that was funded in September 2013.

Cash Flows from Operating Activities. Net cash used for operating activities was $9,278,452 for the nine months ended September 30, 2013 and is primarily attributable to our net loss of $10,615,396, which was offset by $1,294,743 in non-cash activities relating primarily to stock-based compensation, amortization and depreciation expense. Net cash used for operating activities was $2,468,243 for the nine months ended September 30, 2012 and was primarily attributable to our net loss of $3,090,473, a net increase of $123,120 in working capital balances, partially offset by $499,110 in non-cash activities relating to stock-based compensation and depreciation expense.

We expect to continue to incur substantial and increasing losses and have negative net cash flows from operating activities as we seek to: (i) advance our Cynviloq™ asset into a registration trial (a single bioequivalence study) and pursue other potential indications, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (ii) acquire Sherrington and advance its pain drug into clinical trials, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) acquire Concortis, (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs, (vi) comply with our public reporting obligations, and (vii) incur costs related to the Sherrington and Concortis mergers and integrate their operations.

Cash Flows from Investing Activities. Net cash used for investing activities was $744,557 for the nine months ended September 30, 2013 as compared to $491,096 for the nine months ended September 30, 2012. The net cash used related primarily to equipment acquired for research and development activities as well as the rights acquired under the assignment agreement and IgDraSol merger costs.

We expect to increase our investment in laboratory equipment and furnishings as we seek to expand and progress our research and development activities and integrate our acquired assets.

Cash Flows from Financing Activities. Cash flows from financing activities for the nine months ended September 30, 2013 of $11,361,409 was derived from: (i) the issuance of 1,426,333 shares of common stock, in a private placement transaction, at $4.50 per share for aggregate gross proceeds of $6,418,495 in March 2013, and (ii) entering into a $5,000,000 loan and security agreement in September 2013. Cash flows from financing activities for the nine months ended September 30, 2012 of $5,938,231 was derived from the sale of $6,000,000 of our common stock in a private placement transaction in May 2012.

Future Liquidity Needs. From inception through September 30, 2013, we have principally financed our operations through private equity and debt financings with aggregate net proceeds of $26,862,077, as we have not generated any product related revenue from 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 long-term plans for 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 our Cynviloq™ asset into a registration trial (a single bioequivalence study) and pursue other potential indications, including expenses incurred under agreements with CROs and investigative sites that conduct their clinical trials, the cost of acquiring, developing and manufacturing clinical trial materials, and other regulatory operating activities, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (ii) acquire Sherrington and advance its pain drug into clinical trials, (iii) continue to identify and advance a

number of fully human therapeutic antibody and ADC preclinical drug

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candidates, (iv) acquire Concortis, and (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs, (vi) comply with our public reporting obligations, and (vii) incur costs related to the Sherrington and Concortis mergers and integrate their operations.

In October 2013, the Company raised gross proceeds of $34.6 million in a public offering and our common stock commenced trading on The Nasdaq Capital Market. Management believes the Company has the ability to meet all obligations due over the course of the next twelve months.

We plan to continue to fund our losses from operations 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 with the ability to offer up to $100 million of securities. After the October 2013 underwritten offering, we have the ability to offer up to $65.4 million of additional securities. Pursuant to Shelf Registration Statement, 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.

Our actual cash requirements may vary materially from those now planned, however, because of a number of factors, including the actual costs incurred to effect and support the IgDraSol Transactions, Sherrington and Concortis mergers, and related operating activities, the pursuit of development of product candidates, competitive and technical advances, costs of commercializing any potential product candidates, and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If we are unable to raise additional funds when needed, we may not be able to develop any product candidates, we could be required to delay, scale back or eliminate some or all of our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would have a material adverse effect on our business.

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.

Additionally, recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have led to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet liquidity needs.

Off-Balance Sheet Arrangements

Since our inception through September 30, 2013, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

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New Accounting Pronouncements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, as defined by Section 10(f)(1) of Regulation S-K, we are not required to provide the information set forth in this Item.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure 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, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus, including our financial statements and related notes.

Risks Related to Our Financial Position and Capital Requirements

We are a development-stage company subject to all of the risks and uncertainties of a new business, including the risk that we or our partners may never develop, complete development 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. Biopharmaceutical 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, AfDC, resiniferatoxin, Cynviloq™ 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 December 31, 2012 and September 30, 2013, we had an accumulated deficit of $10,950,299 and $21,565,695, respectively. We continue to incur significant research and development and other expenses related to our ongoing and acquired operations. We expect to continue to incur substantial and increasing losses and have negative net cash flows from operating activities as we seek to: (i) advance our Cynviloq asset into a registration trial (a single bioequivalence study) and pursue other potential indications, (ii) incur incremental expenses associated with our efforts to advance a number of potential drug candidates into preclinical development activities, (ii) integrate Sherrington and advance its pain drug into clinical trials, (iii) continue to identify and advance a number of fully human therapeutic antibody and ADC preclinical drug candidates, (iv) acquire Concortis, (v) incur higher salary, lab supply and infrastructure costs incurred in connection with supporting all of the Company s programs, (vi) comply with our public reporting obligations, and (vii) incur costs related to the Sherrington and Concortis mergers and integrate their operations.

As such, we are subject to all of the 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.

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We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

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

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

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

- the progress of the development of our fully-human mAb, AfDC, resiniferatoxin, Cynviloq™ 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.

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Further, the NIH has notified all grant recipients that due to the current Congressional budget sequestration, the NIH may not be able to issue continuation awards, or it may be required to negotiate a reduction in the scope of existing awards to meet the constraints imposed. Additionally, 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 the 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 have a limited operating history and 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. Because we only recently commenced operations, we have a limited operating history upon which you can evaluate our business and prospects. Also, as an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

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

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

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

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the United States 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.

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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.

Clinical 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 inherently 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 biopharmaceutical 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 IG-001, 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. For instance, if bioequivalence, or BE, is not established between Abraxane® and Cynviloq , then additional clinical trials to assess safety and /or efficacy of our formulation may be needed.

In some of our future trials, we may combine Cynviloq or Tocosol® with other therapies such as chemotherapy or immunotherapy. We have not yet tested these combinations.

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

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;

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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.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States 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.

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We plan to seek regulatory approval to commercialize our product candidates both in the United States, 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 most rapid and cost effective access to market approval for Cynviloq™ depends on meeting the conditions for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA.

We are seeking approval for Cynviloq under Section 505(b)(2) of the FFDCA, enacted as part of the Drug Price Competition and Patent Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, which permits applicants to rely in part on preclinical and clinical data generated by third parties. For instance, FDA currently does not know if a BE will be sufficient to support the MBC and NSCLC indications. Sufficiency of the data for approval will be a review issue after an NDA filing.

Specifically, with respect to Cynviloq™, we are relying in part on third party data on paclitaxel, which is the active ingredient in Cynviloq™ and the previously approved products Abraxane® and Taxol®. There can be no assurance that the FDA will not require us to conduct additional preclinical or clinical studies or otherwise obtain new supplementary data with respect to some or all of the data upon which we may rely prior to approving a Cynviloq™ NDA.

Our NDA also relies on prior FDA findings of safety and effectiveness of previously approved products, and we will make certifications in our NDA under Section 505(b)(2) requirements based on the listed patents in the FDA publication Approved Drug Products with Therapeutics Equivalence Evaluations, or the Orange Book, for certain of these referenced products. In the event that one or more patents is listed in the Orange Book for the referenced product after our submission of additional information in support of our NDA for Cynviloq , we may also be required to evaluate the applicability of these patents to Cynviloq and submit additional certifications. A paragraph III certification, stating that a listed patent has not expired, but will expire on a particular date, may delay the approval of Cynviloq until the expiration of the patent. A paragraph IV certification, stating that a listed patent is invalid, unenforceable, or not infringed by Cynviloq may require us to notify the patent owner and the holder of the NDA for the referenced product of the existence of the Cynviloq NDA, and may result in patent litigation against us and the entry of a 30-month stay of FDA ability to issue final approval of the 505(b)(2) NDA for Cynviloq .

Our success also relies, in part, on obtaining Hatch-Waxman marketing exclusivity in connection with any approval of our NDA for Cynviloq . Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of Cynviloq , a product candidate that the FDA views as having the same conditions of approval as Cynviloq (for example, the same indication, the same route of delivery and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Cynviloq as the reference product, for a period of three years from the date of Cynviloq approval, although the FDA may accept and commence review of such applications. This form of exclusivity may not prevent FDA approval of an NDA that relies only on its own data to support the change or innovation. Similarly, if, prior to approval of the Cynviloq NDA, another company obtains approval for a product candidate under, in the view of the FDA, the same conditions of approval that we are seeking for Cynviloq , Cynviloq could be blocked until the other company s three-year Hatch-Waxman marketing exclusivity expires.

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

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

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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. To date, patients treated with Cynviloq have experienced drug-related side effects such as neutropenia, leukopenia, anemia, thrombocytopenia, peripheral neuropathy, myalgia nausea, vomiting, diarrhea, alopecia, rash, pruritus and hypersensitivity reactions. The clinical evaluation of Cynviloq is still in the early stages, but as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw approvals of such product;
- 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.

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

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

We expect to 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. Except for the manufacture and supply of Cynviloq™, 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.

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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 United States 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 United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

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

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

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

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

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

- disruption of our business and diversion of our management s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- inability to motivate key employees of any acquired businesses; and
- assumption of known and unknown liabilities

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;

the clinical indications for which the drug is approved;

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

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

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

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

the relative convenience and ease of administration of Cynviloq™ for clinical practices;

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

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

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

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

If we fail to develop Cynviloq™ for additional indications, our commercial opportunity will be limited.

To date, our initial focus has been on the development of Cynviloq™ for the treatment of MBC and NSCLC. A key element of our strategy is to pursue clinical development of Cynviloq™ for bladder cancer and ovarian cancer, and potentially for other indications. Although we believe there is a large commercial opportunity for the treatment of MBC and NSCLC alone, our ability to generate and grow revenues will be highly dependent on our ability to successfully develop and commercialize Cynviloq™ for the treatment of additional indications. The development of Cynviloq™ for additional indications is prone to the risks of failure inherent in drug development and we cannot provide you any assurance that we will be able to successfully advance any of these programs through the development process. Even if we receive FDA approval to market Cynviloq™ for the treatment of any additional indications, we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize Cynviloq™ for additional indications, our commercial opportunity will be limited and our business prospects will suffer.

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

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid technological advances, both in the United States and internationally. In addition, the competition in the oncology market is intense. For example, our late-stage product candidate, Cynviloq™, may compete directly with a marketed product, Abraxane®, for certain cancer indications. Abraxane® is already approved for MBC, NSCLC and Pancreatic cancer and approval is being pursued for Melanoma cancer. Even if we are able to develop our proprietary platform technology and additional antibody libraries, each will compete with a number of existing and future technologies and product candidates developed, manufactured and marketed by others. Specifically, we will compete against fully

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integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have validated technologies with products already FDA-approved or in various stages of development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing product candidates and technologies generally;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing product candidates; and
- launching, marketing and selling product candidates.

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

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

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

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;

develop relationships with physicians prescribing these products; and

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

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

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If approved, Cynviloq will face competition from less expensive generic products of competitors and, if we are unable to differentiate the benefits of Cynviloq over these less expensive alternatives, we may never generate meaningful product revenues.

Generic paclitaxel therapies are typically sold at lower prices than branded paclitaxel therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, Cynviloq will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. For example, Cynviloq , if approved, will initially face competition from the less expensive generic forms of paclitaxel that are currently available such as Taxol®, and, in the future, would face additional competition from a generic form of Abraxane® when the patents covering it begin to expire in approximately 2022, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of Cynviloq translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

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

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

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

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

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

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

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

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

The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. We are in the early stages of developing potential product candidates, and any candidates that we develop will require extensive preclinical and clinical testing before they will be approved by the FDA or another regulatory authority in a jurisdiction outside the Unites States, if at all. We have not yet developed any product candidate; if we were to do so there are a number of requirements that we would be required to satisfy in order to begin conducting preclinical trials and there can be no assurance that we will develop product candidates or complete the steps necessary to allow us to commence these trials. We cannot predict with any certainty the results of preclinical testing or whether such trials would yield sufficient data to permit us, or those with whom we collaborate, to proceed with clinical development and ultimately submit an application for regulatory approval of our product candidates in the Unites States or abroad, or whether such applications would be approved by the appropriate regulatory agency. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

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

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

Our product development efforts may not be successful.

Our product development efforts for our FIC therapeutic antibodies, AfDC and rIVIG technologies are designed to focus on novel therapeutic approaches and technologies that have not been widely studied. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies. These approaches and technologies may never be successful.

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Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.

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

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

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

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

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

Occasionally, we expect to rely on third parties to gain access to certain antigens.

We expect to gain access to certain antigens through contractual arrangements with leading academic researchers, through companies involved in supplying antigens, by isolating them ourselves, or from publicly available sources. In the event we are unable to access antigens in sufficient quantities, or at all, we may not be able to perform antibody discovery activities for certain antigens, which may have an adverse impact on our business and financial condition.

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

We may have access to very sensitive data regarding patients whose tissue samples are used in our studies. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, create national standards to protect patients medical records and other personal

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information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient s information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to achieve profitability or maintain profitably in the future.

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

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

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

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

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

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

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

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other

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actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

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

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

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

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

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

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

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injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

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

loss of revenues from product sales; and

the inability to commercialize our product candidates.

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

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

Our success will depend upon growing our business and our employee base. Over the next 12 months, we plan to add additional employees to assist us with research and development. Our future growth, if any, may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition, and results of operations.

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

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

International operations may expose us to foreign currency exchange rate fluctuations for all foreign currencies in which we do business and we may be materially adversely affected by these fluctuations.

We formed Sorrento Hong Kong effective December 4, 2012. Sorrento Hong Kong had no operations in 2012 or through September 30, 2013. In the event Sorrento Hong Kong becomes operational, we may have an international subsidiary that operates in a foreign currency which would expose us to foreign currency exchange rate

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fluctuations. We intend to hedge any foreign currency risks associated with potential transactions by entering into forward contracts. Although we may enter into such forward contracts, they may not be adequate to eliminate the risk of foreign currency exchange rate exposures. International operations may also expose us to currency fluctuations as we translate the financial statements of our international subsidiary to U.S. Dollars.

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

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

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

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

- difficulties in identifying and acquiring products, technologies, or businesses that will help our business;
- difficulties in integrating operations, technologies, services, and personnel;
- diversion of financial and managerial resources from existing operations;
- the risk of entering new development activities and markets in which we have little to no experience;
- risks related to the assumption of known and unknown liabilities; and
- risks related to our ability to raise sufficient capital to fund additional operating activities.

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

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

We have a $5.0 million loan and security agreement with Oxford Finance LLC and Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of September 30, 2013, the outstanding principal balance of the Oxford Finance LLC and Silicon Valley Bank loan was $5.0 million. The loan agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or

making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration

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

Risks Related to the Acquisitions of IgDraSol, Sherrington and Concortis.

We may fail to realize the anticipated benefits of the acquisitions of Sherrington, IgDraSol, and Concortis.

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

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

We expect to incur significant additional costs in connection with the acquisitions of IgDraSol and the IgDraSol Transactions, and Concortis and integrating the companies into a single business.

During 2013, we incurred significant legal and professional fees in connection with the IgDraSol, Sherrington and Concortis acquisitions. We expect to incur additional costs integrating the companies operations, higher development and regulatory costs, and personnel, which cannot be estimated accurately at this time. If the total costs of the integration of these companies and advancement of the Cynviloq , Sherrington, and Concortis assets exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

Risks Related to Our Intellectual Property

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

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our proprietary position by maintaining trade secrets and by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We have one issued U.S. patent covering our G-MAB® which expires in 2022 and the examination of its European equivalent is currently in progress. In 2011, several improvement patent applications were filed for our proprietary antibody library technology. However, due to the difficulties of enforcing such antibody library technology, we filed a key patent application in the U.S. only and requested nonpublication. We have commenced generating a patent application portfolio of patents to protect each product candidate in our pipeline. However, the patent position of biopharmaceutical companies involves complex legal and factual questions, and therefore we cannot predict with certainty whether any patent applications that we have filed or that we may file in the future will be approved or any resulting patents will be enforced. In addition, third parties may

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challenge, seek to invalidate or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Any patent applications that we have filed or that we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. In 2012, one issued patent for a formulation of highly insoluble drugs related to Tocosol® expired for failure to pay maintenance fees.

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

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

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

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all, and may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us;
- redesign our products or processes to avoid infringement;
- stop using the subject matter validly claimed in the patents held by others;
- pay damages; and
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our strategic partners or licensees, we or our strategic partners or licensees may be forced to stop or delay developing, manufacturing or selling technologies or potential

products that are claimed to infringe a third party s intellectual property unless that party grants us or our strategic partners or licensees rights to use its intellectual property. Ultimately, we may be unable to develop some of our technologies or potential products or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

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

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

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

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

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

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

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absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

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

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

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

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

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

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

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;

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

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

our dependence on third parties, including CROs;

announcements of the introduction of new products by our competitors;

market conditions in the pharmaceutical and biotechnology sectors;

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

future issuances of common stock or other securities;

the addition or departure of key personnel;

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

actual or anticipated variations in quarterly operating results;

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

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

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

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

issuances of debt or equity securities;

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

trading volume of our common stock;

ineffectiveness of our internal controls;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

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

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

We do not expect to pay cash dividends on our common stock, and investors will be able to receive cash in respect of their shares of our common stock only upon the sale of such shares.

We have no intention in the foreseeable future to pay any cash dividends on our common stock. Therefore, an investor in our common stock may obtain an economic benefit from the common stock only after an increase in its trading price and only then by selling the common stock.

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

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

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

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

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

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

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

As of September 30, 2013, our directors, executive officers and principal stockholders beneficially owned, in the aggregate, approximately 41.3% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

Generally, a change of more than 50% in the ownership of a company s stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2012, we had net operating loss carryforwards aggregating approximately $10.5 million.

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

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

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

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

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

In addition, in November 2013, we adopted a rights agreement that provides that in the event of (i) an acquisition of 15% or more of our outstanding common stock or (ii) an announcement of an intention to make a tender offer or exchange offer for 15% or more of our outstanding common stock, our stockholders, other than the potential acquiror, shall be granted rights enabling them to purchase additional shares of our common stock at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror s ownership position in our shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with our board of directors. Therefore, the rights agreement could make it more difficult for a third party to acquire control of us without the approval of our board of directors.

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
None.

Item 5. Other Information.
None.

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Item 6. Exhibits.

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

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SIGNATURES

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

SORRENTO THERAPEUTICS, INC.

Date: November 14, 2013 By: /s/ Henry Ji, PH.D.
Henry Ji, Ph.D.
Director, Chief Executive Officer & President
(Principal Executive Officer)

Date: November 14, 2013 By: /s/ Richard Glenn Vincent
Richard Glenn Vincent
Director & Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

2.1	Agreement and Plan of Merger between Sorrento Therapeutics, Inc. and IgDraSol, Inc. dated September 9, 2013 (incorporated by reference to Exhibit 2.1 to Form 8-K filed with the SEC on September 11, 2013).
2.2	Agreement and Plan of Merger and Reorganization among Sorrento Therapeutics, Inc., SP Merger Sub, Inc., Sherrington Pharmaceuticals, Inc., Aceras Biomedical LLC, the stockholders of Sherrington Pharmaceuticals, Inc. and Cooley LLP, solely in its capacity as Escrow Agent dated as of October 9, 2013 (incorporated by reference to Exhibit 2.1 to Form 8-K filed with the SEC on October 15, 2013).
2.3	Agreement of Merger among Sorrento Therapeutics, Inc., Catalyst Merger Sub, Inc., Concortis Biosystems, Corp., and Zhenwei Miao and Gang Chen dated as of November 11, 2013 (incorporated by reference to Exhibit 2.1 to Form 8-K filed with the SEC on November 14, 2013).
3.1	Certificate of Designation of Rights, Preferences and Privileges of Series A Junior Participating Preferred Stock of Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on November 12, 2013).
4.1	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on October 21, 2013).
4.2	Rights Agreement, dated as of November 7, 2013 by and between Sorrento Therapeutics, Inc. and Computershare Trust Company, N.A., as rights agent (incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on November 12, 2013).
10.1	Loan and Security Agreement dated as of September 27, 2013 among Oxford Finance LLC, Silicon Valley Bank, Sorrento Therapeutics, Inc. and IgDraSol, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on October 15, 2013).
10.2	Registration Rights Agreement by and among Sorrento Therapeutics, Inc. and the stockholders of Sherrington Pharmaceuticals, Inc. dated as of October 9, 2013 (incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on October 15, 2013)
31.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Richard Glenn Vincent, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, and Richard Glenn Vincent, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document