PUMA BIOTECHNOLOGY, INC.
Form 10-Q
November 10, 2014

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, 2014

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: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	77-0683487
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024

(Address of principal executive offices) (Zip code)

(424) 248-6500

(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 website, 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 filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 30,148,039 shares of Common Stock, par value $0.0001 per share, were outstanding as of November 3, 2014.

PUMA BIOTECHNOLOGY, INC.

- INDEX -

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research organizations and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these state involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2013, that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2014 (unaudited)	December 31, 2013 (note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,263	$ 43,044
Marketable securities	125,597	40,904
Licensor receivable	1,760	9,813
Prepaid expenses and other, current	4,477	2,635
Total current assets	160,097	96,396
Property and equipment, net	1,910	1,684
Prepaid expenses and other, long-term	8,831	5,080
Restricted cash	1,215	1,214
Total assets	$ 172,053	$ 104,374
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 18,448	$ 10,692
Accrued expenses	10,911	8,579
Total current liabilities	29,359	19,271
Deferred rent	1,091	1,116
Total liabilities	30,450	20,387
Commitments and contingencies (note 7)		
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 30,117,819 issued and outstanding at September 30, 2014, and 28,991,289 issued and outstanding at December 31, 2013	3	3
Additional paid-in capital	375,451	223,232
Accumulated other comprehensive income (loss)	(118)	3
Deficit accumulated during the development stage	(233,733)	(139,251)
Total stockholders' equity	141,603	83,987
Total liabilities and stockholders' equity	$ 172,053	$ 104,374

See Accompanying Notes to the Condensed Consolidated Financial Statements

1

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from September 15, 2010 (date of inception) to September 30,
	2014	2013	2014	2013	2014
Operating expenses:					
General and administrative	$3,867	$2,263	$11,296	$6,804	$55,235
Research and development	32,092	12,068	83,387	32,040	178,895
Totals	35,959	14,331	94,683	38,844	234,130
Loss from operations	(35,959)	(14,331)	(94,683)	(38,844)	(234,130)
Other income (expenses):					
Interest income	111	9	223	128	497
Other income (expense)	4	39	(22)	3	(100)
Totals	115	48	201	131	397
Net loss	$(35,844)	$(14,283)	$(94,482)	$(38,713)	$(233,733)
Net loss applicable to common stock	$(35,844)	$(14,283)	$(94,482)	$(38,713)	$(233,733)
Net loss per common share—basic and diluted	$(1.19)	$(0.50)	$(3.16)	$(1.35)	
Weighted-average common shares outstanding—basic and diluted	30,117,819	28,682,055	29,936,254	28,678,439	

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	Three Months Ended		Nine Months Ended		Period from September 15, 2010 (date of inception) to
	September 30,		September 30,		September
	2014	2013	2014	2013	30, 2014
Net loss	$(35,844)	$(14,283)	$(94,482)	$(38,713)	$(233,733)
Other comprehensive income (loss):					
Unrealized gain (loss) on available-for-sale securities	(41)	66	(121)	(8)	(118)
Comprehensive loss	$(35,885)	$(14,217)	$(94,603)	$(38,721)	$(233,851)

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH SEPTEMBER 30, 2014

(in thousands except share data)

(unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development	
	Shares	Amount	Capital	(Loss)	Stage	Total
Balances, beginning	—	$ —	$—	$ —	$ —	$—
Common stock issued for cash at $0.0001 per share	4,000,000	—	—	—	—	—
Paid-in capital	—	—	7	—	—	7
Net loss	—	—	—	—	(7)	(7)
Balance at December 31, 2010	4,000,000	—	7	—	(7)	—
Paid-in capital	—	—	61	—	—	61
Issuance of shares of common stock through private placements at $3.75 per share, net of issuance costs	16,000,000	2	56,739	—	—	56,741
Conversion of stockholder's note payable to equity	40,000	—	150	—	—	150
Stock option compensation	—	—	67	—	—	67
Anti-dilutive warrant	—	—	7,586	—	—	7,586
Net loss	—	—	—	—	(10,233)	(10,233)
Balance at December 31, 2011	20,040,000	2	64,610	—	(10,240)	54,372
Issuance of shares of common stock through equity placement at $16.00 per share, net of issuance costs	8,625,000	1	129,213	—	—	129,214
Stock option compensation	—	—	1,408	—	—	1,408
Anti-dilutive warrant	—	—	18,222	—	—	18,222
Exercises of stock options	11,666	—	45	—	—	45
Net loss	—	—	—	—	(74,352)	(74,352)
Balance at December 31, 2012	28,676,666	3	213,498	—	(84,592)	128,909
Stock option compensation	—	—	7,519	—	—	7,519
Exercises of stock options	314,623	—	2,215	—	—	2,215
	—	—	—	3	—	3

Unrealized gain on available for sale securities						
Net loss	—	—	—	—	(54,659)	(54,659)
Balance at December 31, 2013	28,991,289	3	223,232	3	(139,251)	83,987
Stock option compensation	—	—	22,779	—	—	22,779
Issuance of shares of common stock through equity placement at $122.50 per share, net of issuance costs	1,126,530	—	129,440	—	—	129,440
Unrealized loss on available for sale securities	—	—	—	(121)	—	(121)
Net loss	—	—	—	—	(94,482)	(94,482)
Balance at September 30, 2014	30,117,819	$ 3	$ 375,451	$ (118)	$ (233,733)	$ 141,603

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended		Period from September 15, 2010 (date of inception) to September 30, 2014
	September 30, 2014	2013	
Operating activities:			
Net loss	$(94,482)	$(38,713)	$(233,733)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	438	298	1,137
Build-out allowance received from landlord	—	—	903
Stock option expense	22,779	4,426	31,773
Anti-dilutive warrant	—	—	25,808
Changes in operating assets and liabilities:			
Licensor receivable	8,053	(682)	(1,760)
Prepaid expenses and other	(5,593)	(4,357)	(13,308)
Accounts payable	7,756	9,248	18,448
Accrued expenses	2,332	(11,723)	10,911
Accrual of deferred rent	(25)	34	188
Net cash used in operating activities	(58,742)	(41,469)	(159,633)
Investing activities:			
Purchase of property and equipment	(554)	(435)	(2,023)
Expenditures for leasehold improvements	(110)	(3)	(1,024)
Restricted cash	(1)	(1)	(1,215)
Purchase of available-for-sale securities	(132,260)	(44,385)	(181,607)
Sale/maturity of available-for-sale securities	47,446	—	55,892
Net cash used in investing activities	(85,479)	(44,824)	(129,977)
Financing activities:			
Proceeds from issuance of stockholder's convertible note payable	—	—	150
Net proceeds from issuance of common stock	129,440	—	315,395
Net proceeds from exercise of options	—	146	2,260
Capital contributions by stockholder	—	—	68
Net cash provided by financing activities	129,440	146	317,873

Net increase (decrease) in cash and cash equivalents	(14,781)	(86,147)	28,263
Cash and cash equivalents, beginning of period	43,044	137,408	—
Cash and cash equivalents, end of period	$28,263	$51,261	$28,263
Supplemental disclosures of non-cash investing and financing activities:			
Conversion of stockholder's note payable to common stock	$—	$—	$150

See Accompanying Notes to the Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or Puma, is a development stage biopharmaceutical company based in Los Angeles, California that acquires and develops innovative products for the treatment of various forms of cancer. References in these Notes to Condensed Consolidated Financial Statements to the "Company" refer to Puma Biotechnology, Inc., a private Delaware company formed on September 15, 2010, for periods prior to the Merger (as defined below), which took place on October 4, 2011, and Puma Biotechnology, Inc., a Delaware company formed on April 27, 2007, and formerly known as Innovative Acquisitions Corp., for periods following the Merger. The Company focuses on in-licensing drug candidates that are undergoing or have already completed initial clinical testing for the treatment of cancer and then seeks to further develop those drug candidates for commercial use.

In November 2012, the Company established and incorporated Puma Biotechnology Ltd, a wholly-owned subsidiary, for the sole purpose of serving as Puma's legal representative in the United Kingdom and the European Union in connection with Puma's clinical trial activity in those countries.

Basis of Presentation:

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products. Through September 30, 2014, its primary focus has been the transition of operational responsibility for its lead drug candidate, PB272 (neratinib (oral)), from Pfizer, Inc., or the Licensor, to the Company (see the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and Note 7 to these Condensed Consolidated Financial Statements, for additional information on the license agreement) along with the execution of clinical trials in HER2-positive metastatic breast cancer, HER2-positive neoadjuvant breast cancer, HER2-positive adjuvant breast cancer, as well as clinical trials in advanced cancer patients with tumors that have HER2-mutations, including non-small cell lung cancer, HER2-negative breast cancer, and other solid tumors. The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial information. Accordingly, the financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2014, or for any subsequent period. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013. The condensed consolidated balance sheet at December 31, 2013, has been derived from the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

The Company has reported a net loss of approximately $35.8 million and $94.5 million and negative cash flows from operations of approximately $24.3 million and $58.7 million for the three and nine months ended September 30, 2014, respectively. The net loss from the date of inception, September 15, 2010, to September 30, 2014, amounted to approximately $233.7 million, while the negative cash flows from operations from the date of inception amounted to approximately $159.6 million. For the three and nine months ended September 30, 2014, the Company's net loss was impacted by the amendment to the license agreement with Pfizer signed during July 2014, which resulted in the Company recognizing the expenses incurred in connection with the ongoing clinical trials after December 31, 2013. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process.

The Company's continued operations will depend on its ability to raise funds through various potential sources such as equity and debt financing. Through September 30, 2014, the Company's financing was primarily through public offerings of Company common stock and private equity placements. Given the current and desired pace of clinical development of its product candidates, management estimates that the Company has sufficient cash on hand to fund clinical development through 2015 and into 2016. The Company will need additional financing thereafter until it can achieve profitability, if ever. The Company may choose to raise additional capital before 2016 in order to fund its future development activities. There can be no assurance that such capital will be available on favorable terms, or at all, or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Merger with Public Company:

On September 29, 2011, the Company entered into an agreement and plan of merger, or the Merger Agreement, with Innovative Acquisitions Corp., or IAC, and IAC's wholly-owned subsidiary, IAC Merger Corporation, or Merger Sub. On October 4, 2011, the Company completed a reverse merger in which Merger Sub merged with and into the Company and the Company became a wholly-owned subsidiary of IAC, or the Merger. At the effective time of the Merger, the Company's then issued and outstanding 18,666,733 shares of common stock were exchanged for 18,666,733 shares of common stock of IAC and each share of the Company's common stock that was outstanding immediately prior to the effective time was cancelled, with one share of the Company common stock issued to IAC. Concurrently, IAC redeemed all of its shares from its pre-Merger stockholders in exchange for aggregate consideration of $40,000 paid by the Company. The Company also paid $40,000 for IAC's professional fees associated with the Merger directly to legal counsel for IAC's former stockholders. Following the Merger and the redemption, the Company's prior stockholders owned the same percentage of IAC's common stock as they held of the Company's common stock prior to the Merger.

Upon completion of the Merger, the Company merged with and into IAC, and IAC adopted the Company's business plan and changed its name to "Puma Biotechnology, Inc." Further, upon completion of the Merger, the existing officers and directors of IAC resigned and the existing officers and directors of the Company were appointed officers and directors of IAC.

The Merger was accounted for as a reverse acquisition, with the Company as the accounting acquirer and IAC as the accounting acquiree. The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction in substance, rather than a business combination for accounting purposes. Accordingly, the Company treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. Consideration in the amount of $80,000 paid to the former stockholders of IAC and their attorney was recorded as an other expense item and included in the Company's net loss for the year ended December 31, 2011.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these condensed consolidated financial statements are as follows:

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include the cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period. The value of stock-based compensation includes estimates based on future events, which are difficult to predict. It is at least reasonably possible that a change in the estimates will occur in the near term.

Principles of Consolidation:

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents:

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Licensor Receivable:

Licensor receivable represents the remaining 2013 and prior external “out of pocket” clinical trial costs in excess of an agreed upon “cap” for clinical trials that were ongoing at the time the licensing agreement with the Licensor was reached. In July 2014, the license agreement was amended to make the Company solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013, and to fix the future royalty rate that must be paid to the Licensor upon commercialization in the low to mid teens. The Company has not established a reserve against this receivable as it is deemed to be fully collectible.

Marketable Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses, if material, reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification, or ASC 820, Fair Value Measurement, provides a single definition of fair value and a common framework for measuring fair value as well as new disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

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

Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of September 30, 2014, and December 31, 2013, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

September 30, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents	$17,974	$—	$ —	$17,974

Marketable securities - corporate bonds	—	92,308	—	92,308
Marketable securities - US government		11,502		11,502
Marketable securities - commercial paper	—	21,786	—	21,786
	$17,974	$125,596	$ —	$143,570

December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents	$41,598	$—	$ —	$41,598
Marketable securities - corporate bonds	—	40,904	—	40,904
	$41,598	$40,904	$ —	$82,502

The Company’s investments in short-term investment securities are exposed to price fluctuations. The fair value measurements for short-term investment securities are based upon the quoted price in active markets multiplied by the number of securities owned, exclusive of any transaction costs and without any adjustments to reflect discounts that may be applied to selling a large block of securities at one time.

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company’s cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities

Investor Protection Corporation insured limits at September 30, 2014, were approximately $29.3 million. The Company does not believe it is exposed to any significant credit risk.

Property and Equipment:

Property and equipment are recorded at cost and depreciated over estimated useful lives ranging from three to five years using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of their useful lives or the term of the lease by use of the straight-line method. Maintenance and repair costs are charged to operations as incurred.

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been impairment by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through September 30, 2014.

Research and Development Expenses:

Research and development, or R&D, expenses are charged to operations as incurred. The major components of R&D costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company's accrual policy is to match the recording of expenses in the condensed consolidated financial statements to the actual services received and efforts expended. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying condensed consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

Research and Development Reimbursement:

The license agreement set a "cap" on the amount of external expenses the Company would incur, beginning January 1, 2012, in completing the clinical trials transferred from the Licensor to the Company. The license agreement was

amended in July 2014 which made the Company solely responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. In addition, as part of the amended license agreement, the Company will pay the Licensor a fixed royalty rate in the low to mid teens upon commercialization of licensed products. The license agreement originally stipulated that the Licensor would be responsible for all external expenses associated with the transferred clinical trials and that the Company would invoice for such costs on a quarterly basis. The Licensor had 60 days to review the invoice and supporting documentation. All amounts reimbursed from the licensor represent charges for services provided by third parties and not the Company. Accordingly, the Company has elected to treat the reimbursed costs as “pass-through” expenses billable to the Licensor and as an offset to R&D expenses. R&D expenses are recorded net of any excess cap costs billed to the Licensor. The Company recognized approximately $3.4 million and $13.1 million of excess cap costs during the three months and nine months ended September 30, 2013, respectively. Pursuant to the amendment to the original license agreement, no reduction in the expenses related to the licensor legacy clinical trials that were in excess of a cap on such expenses set forth in the license agreement was recorded in the three and nine months ended September 30, 2014.

Stock-Based Compensation:

Stock option awards:

ASC 718, Compensation-Stock Compensation, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the date of grant, or grant date, and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur; instead, estimated option forfeitures must be calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. Due to its limited history, the Company uses the simplified method to determine the expected life of the option grants.

Performance shares:

The performance shares are valued on the grant date and the fair value of the performance award is equal to the market price of the Company's common stock on the grant date. The performance share expense is recognized based on the Company's estimate of a range of probabilities that the Company's closing common stock price will be lower or higher than the Company's common stock price on the grant date on the vesting dates. Based on the range of probabilities, the expense is calculated and recognized over the three-year vesting period.

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented, as required by ASC 260, Earnings per Share. Diluted earnings per common share are the same as basic earnings per share because the assumed exercise of the Company's outstanding options are anti-dilutive. For the three and nine months ended September 30, 2014, potentially dilutive securities excluded from the calculations were 3,778,307 shares issuable upon exercise of options, 28,411 performance shares issuable upon attainment of stock price objectives over the vesting period of the performance share awards and 2,116,250 shares issuable upon exercise of an outstanding warrant. For the three and nine months ended September 30, 2013, potentially dilutive securities excluded from the earnings per common share calculation were 2,373,309 shares issuable upon exercise of options and 2,116,250 shares issuable upon exercise of an outstanding warrant.

Deferred Rent:

The Company has entered into operating lease agreements for its corporate offices in Los Angeles and South San Francisco that contain provisions for future rent increases, leasehold improvement allowances and rent abatements. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying condensed consolidated balance sheets. Additionally, the Company recorded as deferred rent the cost of the leasehold improvements paid by the landlord, which is amortized on a straight-line basis over the term of the lease.

Recently Issued Accounting Pronouncements:

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09 Revenue from Contracts with Customers, or ASU No. 2014-09, which will supersede nearly all existing revenue recognition guidance under GAAP. ASU No. 2014-09 provides that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU No. 2014-09 allows for either full retrospective or modified retrospective adoption and will become effective for the Company in the first quarter of 2018. The Company is a development stage entity and will evaluate the effects of this update on its consolidated financial statements when it generates revenues.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities, or ASU No. 2014-10, which eliminated certain financial reporting requirements of companies previously identified as development stage entities (Topic 915). The amendments in this ASU simplify accounting guidance by removing all incremental financial reporting requirements for development

stage entities. The amendments also reduce data maintenance and, for those entities subject to audit, audit costs by eliminating the requirement for development stage entities to present inception-to-date information in the statements of income, cash flows, and stockholder equity. For public entities, these amendments begin to be effective for periods after December 31, 2014. Early application of each of the amendments is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). Upon adoption, entities will no longer present or disclose any information required by Topic 915. The Company will adopt this standard in future presentations. The financial impact on the Company is expected to be negligible.

In August 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-15 Presentation of Financial Statements – Going Concern, or ASU No. 2014-15, which provides guidance on how management will evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued. ASU No. 2014-15 will become effective for the Company in the fourth quarter of 2016, although early adoption is allowed. The Company is currently evaluating this guidance and expects the financial impact on the Company to be negligible.

Reclassifications:

Certain amounts for 2013 have been reclassified to conform to the current year's presentation.

Note 3—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Short-term:		
CRO services	$ 1,584	$ 863
Other clinical development	2,463	1,089
Insurance	228	554
Other	202	129