

PUMA BIOTECHNOLOGY, INC.

Form 10-Q

May 12, 2014

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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 March 31, 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**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**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 ☒ 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 ☒ 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 ☒ 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 ☒.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. **30,117,819 shares of Common Stock, par value \$0.0001 per share, were outstanding as of April 29, 2014.**

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**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 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.

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## 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)**

|  | March 31,<br>2014<br>(unaudited) | December 31 ,<br>2013<br>(Note 1) |
|--|----------------------------------|-----------------------------------|
| <b>ASSETS</b>  |                                  |                                   |
| Current assets:  |                                  |                                   |
| Cash and cash equivalents  | \$ 163,380                       | \$ 43,044                         |
| Marketable securities  | 32,734                           | 40,904                            |
| Licensor receivable  | 13,296                           | 9,813                             |
| Prepaid expenses and other, current  | 2,253                            | 2,635                             |
| Total current assets   | 211,663                          | 96,396                            |
| Property and equipment, net  | 1,769                            | 1,684                             |
| Prepaid expenses and other, long-term  | 5,607                            | 5,080                             |
| Restricted cash  | 1,214                            | 1,214                             |
| Total assets   | \$ 220,253                       | \$ 104,374                        |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                  |                                   |
| Current liabilities:   |                                  |                                   |
| Accounts payable   | \$ 15,192                        | \$ 10,692                         |
| Accrued expenses   | 5,051                            | 8,579                             |
| Total current liabilities  | 20,243                           | 19,271                            |
| Deferred rent  | 1,223                            | 1,116                             |
| Total liabilities  | 21,466                           | 20,387                            |
| Stockholders' equity:  |                                  |                                   |
| Common stock \$.0001 par value; 100,000,000 shares authorized; 30,117,819 issued and outstanding at March 31, 2014, and 28,991,289 issued and outstanding at December 31, 2013 | 3                                | 3                                 |
| Additional paid-in capital   | 357,835                          | 223,232                           |
| Accumulated other comprehensive income   | (6)                              | 3                                 |
| Deficit accumulated during the development stage   | (159,045)                        | (139,251)                         |

|  |            |            |
|--|------------|------------|
| Total stockholders' equity                 | 198,787    | 83,987     |
| Total liabilities and stockholders' equity | \$ 220,253 | \$ 104,374 |

See Accompanying Notes to the Condensed Consolidated Financial Statements

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**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(in thousands except per share data)**  
**(unaudited)**

|  | Three Months Ended March 31, |             | Period from  |
|--|------------------------------|-------------|--|
|  | 2014                         | 2013        | September 15, 2010<br>(date of inception) to<br>March 31, 2014 |
| Operating expenses:  |                              |             |  |
| General and administrative                                   | \$ 3,525                     | \$ 2,274    | \$ 47,464  |
| Research and development                                     | 16,294                       | 9,532       | 111,802  |
| Totals   | 19,819                       | 11,806      | 159,266  |
| Loss from operations   | (19,819)                     | (11,806)    | (159,266)  |
| Other income (expenses):                                     |                              |             |  |
| Interest income  | 46                           | 23          | 320  |
| Other income (expense)                                       | (21)                         | 3           | (99)   |
| Totals   | 25                           | 26          | 221  |
| Net loss   | \$ (19,794)                  | \$ (11,780) | \$ (159,045)   |
| Net loss applicable to common stock                          | \$ (19,794)                  | \$ (11,780) | \$ (159,045)   |
| Net loss per common share basic and diluted                  | \$ (0.67)                    | \$ (0.41)   |  |
| Weighted-average common shares outstanding basic and diluted | 29,567,071                   | 28,676,666  |  |

See Accompanying Notes to the Condensed Consolidated Financial Statements



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**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY**

**(A DEVELOPMENT STAGE COMPANY)**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(in thousands)**

**(unaudited)**

|  | Three Months Ended<br>March 31, |             | Period from<br>September 15,<br>2010 (date of<br>inception) to<br>March 31, 2014 |
|--|---------------------------------|-------------|--|
|  | 2014                            | 2013        |  |
| Net loss   | \$ (19,794)                     | \$ (11,780) | \$ (159,045)   |
| Other comprehensive income (loss)                |                                 |             |  |
| Unrealized gain on available-for-sale securities | (9)                             | (25)        | (6)  |
| Comprehensive loss                               | \$ (19,803)                     | \$ (11,805) | \$ (159,051)   |

See Accompanying Notes to the Condensed Consolidated Financial Statements

Table of Contents**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY****(A DEVELOPMENT STAGE COMPANY)****CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****THE PERIOD FROM SEPTEMBER 15, 2010 (DATE OF INCEPTION) THROUGH MARCH 31, 2014****(in thousands except share data)****(unaudited)**

|  | Common Stock |        | Additional      | Accumulated Other Comprehensive | Deficit Accumulated During the | Total    |
|--|--------------|--------|-----------------|---------------------------------|--------------------------------|----------|
|  | Shares       | Amount | Paid-in Capital | Income                          | Development Stage              |          |
| 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    |

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|  |            |      |            |        |              |            |
|--|------------|------|------------|--------|--------------|------------|
| Unrealized gain on available for sale securities   |            |      |            | 3      |              | 3          |
| 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  |            |      | 5,163      |        |              | 5,163      |
| 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   |            |      |            | (9)    |              | (9)        |
| Net loss   |            |      |            |        | (19,794)     | (19,794)   |
| Balance at March 31, 2014  | 30,117,819 | \$ 3 | \$ 357,835 | \$ (6) | \$ (159,045) | \$ 198,787 |

See Accompanying Notes to the Condensed Consolidated Financial Statements

Table of Contents**PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY****(A DEVELOPMENT STAGE COMPANY)****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

|   | Three Months Ended<br>March 31, |             | Period from<br>September 15,<br>2010 (date of<br>inception) to<br>March 31, |
|---|---------------------------------|-------------|---|
|   | 2014                            | 2013        | 2014  |
| Operating activities:   |                                 |             |   |
| Net loss  | \$ (19,794)                     | \$ (11,780) | \$ (159,045)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |             |   |
| Depreciation and amortization   | 133                             | 90          | 832   |
| Build-out allowance received from landlord                                  |                                 |             | 903   |
| Stock based compensation expense  | 5,163                           | 1,175       | 14,157  |
| Anti-dilutive warrant   |                                 |             | 25,808  |
| Changes in operating assets and liabilities:                                |                                 |             |   |
| Licensor receivable   | (3,483)                         | (6,723)     | (13,296)  |
| Prepaid expenses and other  | (145)                           | (1,195)     | (7,860)   |
| Accounts payable  | 4,500                           | 6,405       | 15,192  |
| Accrued expenses  | (3,528)                         | (6,477)     | 5,051   |
| Accrual of deferred rent  | 107                             | 24          | 320   |
| Net cash used in operating activities                                       | (17,047)                        | (18,481)    | (117,938)   |
| Investing activities:   |                                 |             |   |
| Purchase of property and equipment  | (214)                           | (183)       | (1,683)   |
| Expenditures for leasehold improvements                                     | (4)                             |             | (918)   |
| Restricted cash   |                                 | (1)         | (1,214)   |
| Purchase of available-for-sale securities                                   |                                 | (27,095)    | (49,347)  |
| Sale/maturity of available-for-sale securities                              | 8,161                           |             | 16,607  |
| Net cash provided by (used in) in investing activities                      | 7,943                           | (27,279)    | (36,555)  |
| 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                                       |                                 |             | 2,260   |
| Capital contributions by stockholder  |                                 |             | 68  |

|  |            |           |            |
|--|------------|-----------|------------|
| Net cash provided by financing activities                                | 129,440    |           | 317,873    |
| Net increase (decrease) in cash and cash equivalents                     | 120,336    | (45,760)  | 163,380    |
| Cash and cash equivalents, beginning of period                           | 43,044     | 137,408   |            |
| Cash and cash equivalents, end of period                                 | \$ 163,380 | \$ 91,648 | \$ 163,380 |
| 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

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**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 and, through March 31, 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, for details of 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 \$19.8 million and negative cash flows from operations of approximately \$17.0 million for the three months ended March 31, 2014. The net loss from the date of inception, September 15, 2010, to March 31, 2014, amounted to approximately \$159.0 million, while the negative cash flows

from operations from the date of inception amounted to approximately \$117.9 million. Currently, the Company's negative cash flows from operations are being adversely impacted by a timing difference related to the payment of cap cost expenses to vendors and receipt from the Licensor for said expenses (see Note 2 Significant Accounting Policies: Research and Development Reimbursement). 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 March 31, 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.

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**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 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. The licensing agreement allows the Company to bill the Licensor for all external out of pocket costs in excess of the cap cost on a quarterly basis. The Licensor, per the license agreement, has 60 days to review the invoice and supporting documentation. Licensor receivable includes both invoiced and non-invoiced costs in excess of the cap. The Company has not established a reserve against this receivable (approximately \$13.3 million and \$9.8 million at March 31, 2014 and 2013, respectively).

**Table of Contents****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 March 31, 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):

| March 31, 2014                          | Level 1    | Level 2 | Level 3 | Total      |
|---|------------|---------|---------|------------|
| Cash equivalents                        | \$ 156,010 | \$      | \$      | \$ 156,010 |
| Marketable securities - corporate bonds |            | 23,650  |         | 23,650     |

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|  |            |           |         |            |
|--|------------|-----------|---------|------------|
| Marketable securities commercial paper |            | 9,084     |         | 9,084      |
|  | \$ 156,010 | \$ 32,734 | \$      | \$ 188,744 |
| 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.

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### **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 March 31, 2014, were approximately \$164.6 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 March 31, 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 deposits 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 licensing 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 stipulates 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 has 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 research and development expenses. R&D expenses are recorded net of any excess cap costs billed to the Licensor. The Company recognized approximately \$3.5 million and \$4.6 million of excess cap costs during the three months ended March 31, 2014 and 2013, respectively.

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**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 3-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 months ended March 31, 2014, potentially dilutive securities excluded from the calculations were 3,059,849 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 months ended March 31, 2013, potentially dilutive securities excluded from the earnings per common share calculation were 2,145,584 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.



**Table of Contents****Note 3 Prepaid Expenses and Other:**

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

|                            | March 31,<br>2014 | December 31,<br>2013 |
|----------------------------|-------------------|----------------------|
| Short-term:                |                   |                      |
| CRO services               | \$ 654            | \$ 863               |
| Other clinical development | 973               | 1,089                |
| Insurance                  | 443               | 554                  |
| Other                      | 183               | 129                  |
|                            | 2,253             | 2,635                |
| Long-term:                 |                   |                      |
| CRO services               | 1,490             | 1,509                |
| Other clinical development | 3,891             | 3,359                |
| Insurance                  | 164               | 142                  |
| Other                      | 62                | 70                   |
|                            | 5,607             | 5,080                |
| Totals                     | \$ 7,860          | \$ 7,715             |

**Note 4 Property and Equipment:**

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

|   | March 31,<br>2014 | December 31,<br>2013 |
|---|-------------------|----------------------|
| Leasehold improvements                          | \$ 1,020          | \$ 914               |
| Computer equipment                              | 961               | 874                  |
| Telephone equipment                             | 86                | 82                   |
| Furniture and fixtures                          | 534               | 513                  |
|   | 2,601             | 2,383                |
| Less: accumulated depreciation and amortization | (832)             | (699)                |
| Totals  | \$ 1,769          | \$ 1,684             |



**Table of Contents****Note 5 Accrued Expenses:**

Accrued expenses consisted of the following (in thousands):

|                                    | March 31,<br>2014 | December 31,<br>2013 |
|------------------------------------|-------------------|----------------------|
| Accrued CRO/licensor services      | \$ 1,784          | \$ 4,801             |
| Accrued other clinical development | 1,271             | 2,369                |
| Accrued legal fees                 | 252               | 84                   |
| Accrued compensation               | 1,717             | 1,066                |
| Other                              | 27                | 259                  |
|                                    | \$ 5,051          | \$ 8,579             |

Accrued CRO/licensor services represent the Company's estimate of such costs as of March 31, 2014, and will be adjusted in the period the actual costs become known. Accrued compensation includes estimated bonus and earned but unused vacation for full-time employees. When actual performance bonuses are paid out to employees on the employee's anniversary of hire, the bonus expense will be adjusted to reflect the actual expense for the year. Additionally, vacation is accrued at the rate the employee earns vacation and reduced as the vacation is used by the employee.

**Note 6 Stockholders' Equity:****Common stock:**

On February 14, 2014, the Company completed an underwritten public offering of 1,126,530 shares of the Company's common stock (including an additional 146,938 shares of Company common stock issued and sold pursuant to the underwriters' option to purchase additional shares), par value \$0.0001 per share, at a price of \$122.50 per share, less the underwriting discount. The net proceeds received by the Company were approximately \$129.4 million after deducting the underwriting discount and offering expenses payable by the Company.

**Stock-Based Compensation:**

The Company's 2011 Incentive Award Plan, or the 2011 Plan, was adopted by the Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation such as performance shares. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. The performance shares are valued at market value less par value and vest over three years with the number of shares to be issued determined by the market price on the vesting date. The award determined a maximum number of shares which could be issued. Through March 31, 2014, a total of 3,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

Employee stock-based compensation for the three months ended March 31, 2014 and 2013, were as follows:

|  | 2014       | 2013       |
|--|------------|------------|
| Stock-based compensation:                      |            |            |
| Options-                                       |            |            |
| Research and development                       | \$ 3,226   | \$ 737     |
| General and administrative, or G&A             | 1,341      | 438        |
| Performance shares R&D                         | 596        |            |
| Total share-based compensation expense         | \$ 5,163   | \$ 1,175   |
| Impact on basic and diluted net loss per share | \$ 0.17    | \$ 0.04    |
| Weighted average shares (basic and diluted)    | 29,567,071 | 28,676,666 |

**Performance shares:**

During January 2014, performance share awards were granted to certain employees that provide for a maximum of 28,411 common stock shares to be issued. These shares vest over three years on the first, second and third anniversary of December 15, 2013. On each vesting date, if the Company's closing common stock per share price is equal to \$102.46 per share, one-third of the 28,411 shares will be awarded. If the Company's closing common stock price is either lesser or greater than \$102.46 per share, the number of common stock shares to be issued will be adjusted to be less than one-third of the 28,411 shares. No shares will be awarded if the Company's closing common stock price is less than \$47.53 per share at the vesting dates. 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 \$102.46 on the vesting dates. Based on the range of probabilities, the expense is calculated and recognized over the 3-year vesting period.

**Stock options:**

The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2 Significant Accounting Policies) with the following weighted-average assumptions used during the three months ended March 31, 2014 and 2013:

|                         | 2014  | 2013  |
|-------------------------|-------|-------|
| Dividend yield          | 0.0%  | 0.0%  |
| Expected volatility     | 81.3% | 86.4% |
| Risk-free interest rate | 1.8%  | 1.0%  |
| Expected life in years  | 5.85  | 5.85  |

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Activity with respect to options granted under the 2011 Plan is summarized as follows:

|   | Shares    | Weighted<br>Average<br>Exercise<br>Price | Weighted Average<br>Remaining<br>Contractual<br>Term<br>(years) | Aggregate<br>Intrinsic<br>Value (in<br>thousands) |
|---|-----------|--|---|---|
| Outstanding at December 31, 2011  |           |  |   |   |
| Options granted in the period ended<br>March 31, 2012, for which compensation<br>was recognized during 2011 | 670,000   | \$ 3.75                                  |   |   |
| Granted during 2012   | 1,278,000 | \$ 11.48                                 |   |   |
| Forfeited during 2012   | (30,000)  | \$ 3.75                                  |   |   |
| Exercised during 2012   | (11,666)  | \$ 3.75                                  |   | \$ 190  |
| Outstanding at December 31, 2012  | 1,906,334 | \$ 8.93                                  |   |   |
| Granted during 2013   | 1,032,375 | \$ 44.77                                 |   |   |
| Forfeited during 2013   | (19,862)  | \$ 11.60                                 |   |   |
| Exercised during 2013   | (314,623) | \$ 7.29                                  |   | \$ 23,525   |
| Outstanding at December 31, 2013  | 2,604,224 | \$ 23.31                                 |   |   |
| Granted during 2014   | 470,625   | \$ 106.86                                |   |   |
| Forfeited during 2014   | (15,000)  | \$ 33.95                                 |   |   |
| Exercised during 2014   |           | \$                                       |   |   |
| Outstanding at March 31, 2014   | 3,059,849 | \$ 35.52                                 | 8.8   | \$ 214,356  |
| Unvested at March 31, 2014  | 2,048,117 | \$ 48.39                                 | 9.1   | \$ 118,565  |
| Exercisable at March 31, 2014   | 1,011,732 | \$ 9.46                                  | 8.2   | \$ 95,791   |

At March 31, 2014, total estimated unrecognized employee compensation cost related to non-vested stock options and performance shares granted prior to that date was approximately \$63.6 million and \$2.0 million, respectively. This unrecognized expense is expected to be recognized over a weighted-average period of 2.6 years for stock options and 1.8 years for performance shares. The weighted-average grant date fair value of options granted during the three months ended March 31, 2014 and 2013, was \$73.89 per share and \$18.84 per share, respectively.

|                                       | Shares    | Weighted<br>Average<br>Grant-Date<br>Fair Value |
|---------------------------------------|-----------|---|
| Stock options                         |           |   |
| Nonvested shares at December 31, 2013 | 1,838,633 | \$ 20.18  |
| Granted                               | 470,625   | 73.89   |
| Vested/Issued                         | (246,141) | 10.71   |

|                                    |           |          |
|------------------------------------|-----------|----------|
| Forfeited                          | (15,000)  | 24.45    |
| Nonvested shares at March 31, 2014 | 2,048,117 | \$ 33.63 |

**Note 7 401(k) Savings Plan:**

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately \$86,800 and \$48,600 for the three months ended March 31, 2014 and 2013, respectively.

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**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with our audited financial statements and the notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2013.

Unless otherwise provided in this Quarterly Report, references to the Company, we, us, and our refer to Puma Biotechnology, Inc., a Delaware corporation formed on April 27, 2007 and formerly known as Innovative Acquisitions Corp., together with its wholly-owned subsidiary, Puma Biotechnology Ltd. All references to Former Puma refer to Puma Biotechnology, Inc., a privately held Delaware corporation formed on September 15, 2010, that merged with and into us on October 4, 2011. This transaction was accounted for as a reverse acquisition whereby Former Puma was deemed to be the acquirer for accounting and financial reporting purposes and we were deemed to be the acquired party. Consequently, our financial statements prior to the reverse merger transaction reflect the assets and liabilities and the historical operations of Former Puma from its inception on September 15, 2010 through the closing of the reverse merger transaction on October 4, 2011. Our financial statements after completion of the reverse merger transaction include the assets and liabilities of us and Former Puma and the operations of Former Puma and us.

**Overview**

We are a development stage biopharmaceutical company based in Los Angeles, California with a focus on the acquisition, development and commercialization of innovative products to enhance cancer care. We aim to acquire proprietary rights to these products, by license or otherwise, fund their research and development and bring the products to market. Our efforts and resources to date have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. As a development stage company, we have had no product sales to date, and we will have no product sales until we receive approval from the United States Food and Drug Administration, or FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Developing pharmaceutical products, however, is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to receive approval of a product candidate until approximately 2015.

We currently license the rights to three drug candidates:

PB272 (neratinib (oral)), which we are developing for the treatment of patients with advanced breast cancer patients, non-small cell lung cancer and HER2 mutation-positive solid tumors;

PB272 (neratinib (intravenous)), which we are developing for the treatment of advanced cancer patients; and

PB357, which we believe can serve as a backup compound to PB272, and which we are evaluating for further development.

A large portion of our expenses to date have been related to the clinical development of our lead product candidate, PB272 (neratinib (oral)), and the transition of the neratinib program from the licensor. During this transition period,

we built up our infrastructure and assumed responsibility for the neratinib program.

The license agreement for PB272 established a limit for our expenses related to the Pfizer-initiated clinical trials for PB272 that were ongoing at the time of the agreement. This capped our out-of-pocket costs incurred in conducting these existing trials beginning January 1, 2012. We reached the cost cap during the fourth quarter of 2012, which resulted in a reduction of our R&D expenses for the fourth quarter of 2012. Additionally, our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)) and PB357, our second and third product candidates, respectively, we expect our R&D expenses and expenses related to our third-party contractors will continue to increase.

To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance R&D will increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. Our major sources of working capital have been proceeds from public offerings of our common stock and sales of our common stock in private placements.

**Table of Contents****Critical Accounting Policies**

As of the date of the filing of this quarterly report, we believe there have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2014, from our accounting policies at December 31, 2013, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

**Summary of Expenses**

General and administrative, or G&A, expenses consist primarily of salaries and related personnel costs (including stock-based compensation expense), professional fees, business insurance, rent, general legal activities, and other corporate expenses.

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials, and clinical trials. During the three months ended March 31, 2014, our R&D expenses consisted primarily of CRO costs, other clinical development costs and salaries and related personnel costs (including stock-based compensation expenses). We expense our R&D costs as they are incurred.

**Results of Operations**

The following summarizes our results of operations for the three months ended March 31, 2014 and 2013.

*General and administrative expenses:*

For the three months ended March 31, 2014, G&A expenses were approximately \$3.5 million, compared to approximately \$2.3 million for the three months ended March 31, 2013. G&A expenses for the three months ended March 31, 2014 and 2013 were as follows:

| <b>General and administrative expenses<br/>(in thousands)</b> | <b>Three Months Ended<br/>March 31,</b> |                 | <b>Percentage<br/>change<br/>2014/2013</b> |
|---|---|-----------------|--|
|   | <b>2014</b>                             | <b>2013</b>     |  |
| Payroll and related costs                                     | \$ 751                                  | \$ 576          | 30%  |
| Professional fees and expenses                                | 589                                     | 667             | -12%                                       |
| Facility and equipment costs                                  | 417                                     | 315             | 32%  |
| Employee stock-based compensation expense                     | 1,341                                   | 438             | 206%                                       |
| Insurance and business licenses/taxes                         | 176                                     | 106             | 66%  |
| Other   | 251                                     | 172             | 46%  |
|   | <b>\$ 3,525</b>                         | <b>\$ 2,274</b> | <b>55%</b>                                 |

The increase in G&A expenses for the three months ended March 31, 2014, compared to the three months ended March 31, 2013, consisted primarily of an increase in employee stock-based compensation of approximately \$0.9 million and an increase in payroll and related costs of approximately \$0.2 million. These increases to employee stock-based compensation and payroll and related costs were a result of an increase in headcount in G&A from eight full time employees in the three months ended March 31, 2013 to 13 full time employees in the three months ended March 31, 2014. Additionally, facility and equipment costs increased approximately \$0.1 million from approximately

\$0.3 million for the three months ended March 31, 2013 to approximately \$0.4 million for the three months ended March 31, 2014, due to the expansion of our Los Angeles facility in 2014. Insurance and business licenses/taxes increased approximately \$0.1 million for the three months ended March 31, 2014, compared to the three months ended March 31, 2013, due to an increase in directors and officers insurance and corporate liability insurance relating to the growth of the Company. Offsetting these increases was a decrease in professional fees and expenses from approximately \$0.7 million to approximately \$0.6 million for the three months ended March 31, 2013 and 2014, respectively. This decrease in professional fees and expenses was made up of a decrease in consulting fees of approximately \$93,000 mostly due to a one-time recruiting fee for the addition of a member of our Board of Directors and one-time fees for the enhancement of our company website in the first quarter of 2013, a decrease in legal fees of approximately \$47,000 offset by an increase in audit fees of approximately \$29,000 and an increase in fees paid to members of our Board of Directors of approximately \$38,000. Prior to 2014, our Board of Directors did not receive cash compensation for their services.



**Table of Contents***Research and development expenses:*

For the three months ended March 31, 2014, R&D expenses were approximately \$16.3 million, compared to approximately \$9.5 million for the three months ended March 31, 2013. R&D expenses for the three months ended March 31, 2014 and 2013 were as follows:

| <b>Research and development expenses<br/>(in thousands)</b> | <b>Three Months Ended<br/>March 31,</b> |             | <b>Percentage<br/>change<br/>2014/2013</b> |
|---|---|-------------|--|
|   | <b>2014</b>                             | <b>2013</b> |  |
| Outside CRO/licensor services                               | \$ 3,931                                | \$ 3,529    | 11%  |
| Outside other clinical development                          | 3,747                                   | 2,498       | 50%  |
| Internal regulatory affairs and quality assurance           | 1,610                                   | 1,331       | 21%  |
| Internal clinical development                               | 2,997                                   | 1,332       | 125%                                       |
| Internal chemical manufacturing                             | 187                                     | 105         | 78%  |
| Employee stock-based compensation                           | 3,822                                   | 737         | 419%                                       |
|   | \$ 16,294                               | \$ 9,532    | 71%  |

For the three months ended March 31, 2014, R&D expenses increased approximately \$6.8 million. The majority of this increase was due to an increase in employee stock-based compensation of approximately \$3.1 million, an increase in internal clinical development of approximately \$1.7 million, an increase in internal regulatory affairs and quality assurance of approximately \$0.3 million and an increase in internal chemical manufacturing of approximately \$0.1 million. These increases are due to increases in full time employees for R&D from 50 for the three months ended March 31, 2013, to 73 for the three months ended March 31, 2014. We expect to continue to hire additional employees focused on R&D activities in support of additional Company-initiated clinical trials during 2014. Outside CRO/licensor services increased from approximately \$3.5 million for the three months ended March 31, 2013, to approximately \$3.9 million for the three months ended March 31, 2014. This increase is due to increased activity in Company-sponsored clinical trials. Additionally, outside other clinical development relating to the development of our lead drug candidates increased to approximately \$3.7 million for the three months ended March 31, 2014, from approximately \$2.5 million for the three months ended March 31, 2013. This increase of approximately \$1.2 million is due to an increase of approximately \$0.7 million for data management consultants and services, an increase of approximately \$0.3 million in clinical operations consultants and services, and an increase of approximately \$0.2 for clinical research and development consultants and services.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial and to increase, they are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

the number of trials and studies in a clinical program;

the number of patients who participate in the trials;

the number of sites included in the trials;

the rates of patient recruitment and enrollment;

the duration of patient treatment and follow-up;

the costs of manufacturing our drug candidates; and

the costs, requirements, timing of, and ability to secure regulatory approvals.

**Table of Contents***Interest income:*

For the three months ended March 31, 2014, we recognized approximately \$46,000 in interest income compared to approximately \$23,000 for the three months ended March 31, 2013. This increase in interest income is due to having additional funds in the money market account as a result of the public offering of our common stock in February 2014. Based on market conditions, we placed our excess funds in money market accounts, high yield savings accounts and other marketable securities, pursuant to our investment policy.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of March 31, 2014, and is intended to supplement the more detailed discussion that follows:

|  | March 31,<br>2014                       | December 31,<br>2013                    |
|--|---|---|
| Liquidity and capital resources (in thousands) |   |   |
| Cash and cash equivalents                      | \$ 163,380                              | \$ 43,044                               |
| Marketable securities                          | 32,734                                  | 40,904                                  |
| Working capital                                | 191,420                                 | 77,125                                  |
| Stockholders' equity                           | 198,787                                 | 83,987                                  |
|  | Three Months Ended<br>March 31,<br>2014 | Three Months Ended<br>March 31,<br>2013 |
| Cash provided by (used in):                    |   |   |
| Operating activities                           | \$ (17,047)                             | \$ (18,481)                             |
| Investing activities                           | 7,943                                   | (27,279)                                |
| Financing activities                           | 129,440                                 |   |
| Increase (decrease) in cash                    | \$ 120,336                              | \$ (45,760)                             |

*Operating Activities:*

For the three months ended March 31, 2014, and the three months ended March 31, 2013, we reported net loss of approximately \$19.8 million and \$11.8 million, respectively, and cash flows used in operating activities of approximately \$17.0 million and \$18.5 million, respectively. Our net loss from Former Puma's date of inception, September 15, 2010, through March 31, 2014, amounted to approximately \$159.0 million, while negative cash flow from operating activities amounted to approximately \$117.9 million for the same period.

For the three months ended March 31, 2014, the net cash used in operating activities, noted above, consisted of approximately \$14.5 million of net loss excluding non-cash items such as depreciation and stock option expense, an increase in Licensor receivable of approximately \$3.5 million and an increase of approximately \$0.1 million in prepaid expenses and other assets. Accrued expenses and accounts payable increased approximately \$1.0 million during the three months ended March 31, 2014, due to increased activity in our clinical trials during the three months ended March 31, 2014. The increase in Licensor receivable (see Note 2 Significant Accounting Policies: Research and Development Reimbursement) represents external charges for services provided by third parties pertaining to the legacy clinical trials. We did not receive payment during the three months ended March 31, 2014, on the licensor

receivable relating to balances as of December 31, 2013. A payment of approximately \$4.7 million was received during April 2014. We anticipate continuing to receive payments for the remaining outstanding amounts in accordance with the terms of the license agreement. Pursuant to the license agreement, the Licensor has 60 days to review the invoices and supporting documentation.

For the three months ended March 31, 2013, the net cash used in operating activities, noted above, consisted of approximately \$10.5 million of net loss excluding non-cash items such as depreciation and stock option expense, increased by a reduction in accounts payable and accrued expenses of approximately \$0.1 million. Further increasing the net loss to arrive at the net cash used in operating activities was an increase in licensor receivable of approximately \$6.7 million. During the three months ended March 31, 2013, we did not receive payment from the licensor as they reviewed our December 31, 2012 invoice. We began receiving payments in June 2013. Finally, an increase in prepaid expenses of approximately \$1.2 million made up the remaining cash used in operating activities as we made advance payments to CROs and other service providers as we ramped up our Phase II and Phase III trials.

*Investing Activities:*

During the three months ended March 31, 2014, net cash received from investing activities was approximately \$7.9 million. This was made up of approximately \$8.1 million of excess cash in corporate bonds that matured and will be reinvested pursuant to our investment policy and offset by \$0.2 million used to purchase of property and equipment, compared to approximately \$27.1 million for the purchase of available-for-sale securities and \$0.2 million in the purchase of property and equipment during the three months ended March 31, 2013.

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### *Financing Activities:*

During the three months ended March 31, 2014, we received proceeds of approximately \$129.4 million from the closing of the February 2014 public offering of our common stock. We did not engage in financing activities for the three months ended March 31, 2013.

### *Current and Future Financing Needs:*

We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our R&D efforts. Given the current and desired pace of clinical development of our six product candidates, over the next 12 months we estimate that our R&D spending will be approximately \$60 million to \$65 million, excluding stock-based compensation. We anticipate spending approximately \$7 million to \$8 million for general and administrative expenses over the next 12 months, excluding stock-based compensation. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control.

While we believe that the approximately \$196.1 million in cash, cash equivalents and marketable securities and the \$13.3 million licensor receivable as of March 31, 2014, will be sufficient to enable us to meet our anticipated expenditures through 2015 and into 2016, we may seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or licensing arrangements. We expect to continue incurring significant losses for the foreseeable future and our continuing operations will depend on whether we are able to raise additional funds through additional equity or debt financing or by entering into a strategic alliance with a third party concerning one or more of our product candidates. Through March 31, 2014, a significant portion of our financing has been through public offerings and private placements of our equity securities. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital raised will be sufficient to meet our needs. Further, in light of current economic conditions, including the lack of access to the capital markets being experienced by small companies, particularly in our industry, there can be no assurance that such capital will be available to us on favorable terms or at all. If we are unable to raise additional funds in the future, we may be forced to delay or discontinue the development of one or more of our product candidates and forego attractive business opportunities. Any additional sources of financing will likely involve the sale of our equity securities, which will have a dilutive effect on our stockholders.

In addition, we have based our estimate of funding our capital requirements on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we would be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

### **Adjusted Statement of Operations:**

The following tables present our operating results, as calculated in accordance with the accounting principles generally accepted in the United States, or GAAP, as adjusted to remove the impact of employee stock-based compensation and the outside CRO/Licensors services and outside clinical development costs associated with the licensor legacy clinical trials that we are in the process of completing. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures. We believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. The majority of the cost associated with the licensor legacy clinical trials related to external costs that we were responsible for but that were subject to a cap.

**Table of Contents****Reconciliation of GAAP and Non-GAAP Financial Information****(in thousands except share and per share data)**

|  | GAAP Measure<br>(Reported)<br>Three Months<br>Ended<br>March 31,<br><br>2014 | Expense Adjustments<br>Stock-based<br>compensation | Licensors<br>legacy<br>clinical<br>trials | Non-GAAP Measure<br>Three Months<br>Ended<br>March 31,<br><br>2014 |
|--|--|--|---|--|
| Operating expense:   |  |  |   |  |
| General and administrative                                   | \$ 3,525   | (1,341)  | \$  | \$ 2,184   |
| Research and development                                     | 16,294   | (3,822)  |   | 12,472   |
| Loss from operations   | (19,819)   | 5,163  |   | (14,656)   |
| Other income (expense):                                      |  |  |   |  |
| Interest income  | 46   |  |   | 46   |
| Other expense  | (21)   |  |   | (21)   |
| Totals   | 25   |  |   | 25   |
| Net loss   | \$ (19,794)  | \$ 5,163   | \$  | \$ (14,631)  |
| Net loss applicable to common stock                          | \$ (19,794)  | \$ 5,163   | \$  | \$ (14,631)  |
| Net loss per common share basic and diluted                  | \$ (0.67)  | \$ 0.17  | \$  | \$ (0.50)  |
| Weighted-average common shares outstanding basic and diluted | 29,567,071   | 29,567,071   | 29,567,071                                | 29,567,071   |

|                            | GAAP Measure<br>(Reported)<br>Three Months<br>Ended<br>March 31,<br><br>2013 | Expense Adjustments<br>Stock-based<br>compensation | Licensors<br>legacy<br>clinical<br>trials | Non-GAAP Measure<br>Three Months<br>Ended<br>March 31,<br><br>2013 |
|----------------------------|--|--|---|--|
| Operating expense:         |  |  |   |  |
| General and administrative | \$ 2,274   | \$ (438)   | \$  | \$ 1,836   |
| Research and development   | 9,532  | (737)  | (275)                                     | 8,520  |
| Loss from operations       | (11,806)   | 1,175  | 275                                       | (10,356)   |

|  |             |            |            |             |
|--|-------------|------------|------------|-------------|
| Other income (expense):                                      |             |            |            |             |
| Interest income  | 23          |            |            | 23          |
| Other expense  | 3           |            |            | 3           |
| Totals   | 26          |            |            | 26          |
| Net loss   | \$ (11,780) | \$ 1,175   | \$ 275     | \$ (10,330) |
| Net loss applicable to common stock                          | \$ (11,780) | \$ 1,175   | \$ 275     | \$ (10,330) |
| Net loss per common share basic and diluted                  | \$ (0.41)   | \$ 0.04    | \$ 0.01    | \$ (0.36)   |
| Weighted-average common shares outstanding basic and diluted | 28,676,666  | 28,676,666 | 28,676,666 | 28,676,666  |



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### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet agreements, as defined by SEC regulations.

### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalents and available-for-sale investments in a variety of securities, which may include investment grade commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. We do not purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of March 31, 2014, our investments consisted primarily of corporate obligations. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or 10% decrease in interest rates due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

### **Item 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (the Company's principal executive officer) and Senior Vice President, Finance and Administration (the Company's principal financial and accounting officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2014. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration have concluded that these disclosure controls and procedures were effective as of March 31, 2014.

#### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

We are not involved in any material pending legal proceedings. Additionally, we are not aware of any contemplated proceedings against us by any governmental authority.

**Item 1A. RISK FACTORS**

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013, which was filed with the SEC on March 3, 2014, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There has been no material change in our risk factors subsequent to the filing of our Annual Report. However, the risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**Recent Sales of Unregistered Securities**

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the quarter ended March 31, 2014.

**Use of Proceeds from the Sale of Registered Securities**

On October 18, 2012, our Registration Statement on Form S-1, as amended (File No. 333-184187), was declared effective for our first registered offering. As a result of the offering, we received net proceeds of approximately \$129.2 million. Through March 31, 2014, approximately \$95.8 million of the net proceeds from the offering have been used to fund the ongoing clinical programs for our lead drug candidate and for other general corporate purposes. We have invested the unused proceeds from the offering in a variety of capital preservation investments, including money market funds and short-term, investment grade, interest-bearing securities. There has been no material change in our planned use of proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

Neither we nor any affiliated purchasers within the definition of Rule 10b-18(a)(3) made any purchases of our equity securities during the quarter ended March 31, 2014.

**Item 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Item 5. OTHER INFORMATION**

None.

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**Item 6. EXHIBITS**

(a) Exhibits required by Item 601 of Regulation S-K.

| <b>Exhibit</b> | <b>Description</b>  |
|----------------|---|
| 31.1           | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 |
| 31.2           | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 |
| 32.1           | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 32.2           | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |
| 101.INS        | XBRL Instance Document  |
| 101.SCH        | XBRL Taxonomy Extension Schema  |
| 101.CAL        | XBRL Taxonomy Extension Calculation Linkbase  |
| 101.DEF        | XBRL Taxonomy Extension Definition Linkbase   |
| 101.LAB        | XBRL Taxonomy Extension Label Linkbase  |
| 101.PRE        | XBRL Taxonomy Extension Presentation Linkbase   |

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**SIGNATURES**

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

**PUMA BIOTECHNOLOGY, INC.**

Date: May 12, 2014

By: /s/ Alan H. Auerbach  
Alan H. Auerbach  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 12, 2014

By: /s/ Charles R. Eyler  
Charles R. Eyler  
Senior Vice President, Finance and Administration  
and Treasurer  
(Principal Financial and Accounting Officer)