

INTERCEPT PHARMACEUTICALS INC  
Form 10-Q  
May 09, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

**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: 001-35668**

**INTERCEPT PHARMACEUTICALS, INC.**

**(Exact Name of Registrant as Specified in Its Charter)**

|   |  |
|---|--|
| <b>Delaware</b>   | <b>22-3868459</b>                                  |
| <b>(State or Other Jurisdiction of<br/>Incorporation or Organization)</b> | <b>(I.R.S. Employer<br/>Identification Number)</b> |
| <b>450 West 15<sup>th</sup> Street, Suite 505</b>                         | <b>10011</b>                                       |
| <b>New York, NY</b>   | <b>(Zip Code)</b>                                  |
| <b>(Address of Principal Executive Offices)</b>                           |  |

**(646) 747-1000**

**(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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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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

As of April 30, 2014, there were 21,087,357 shares of common stock, \$0.001 par value per share, outstanding.

**Intercept Pharmaceuticals, Inc.**

**(A Development Stage Company)**

**INDEX**

**PART I  
FINANCIAL INFORMATION**

|  |    |
|--|----|
| Item 1. <u>Financial Statements</u>  | 4  |
| <u>Condensed Consolidated Balance Sheets at December 31, 2013 and March 31, 2014 (unaudited)</u>   | 4  |
| <u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month periods ended March 31, 2013 and 2014 (unaudited) and the period from September 4, 2002 (inception) through March 31, 2014 (unaudited)</u> | 5  |
| <u>Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2013 and 2014 (unaudited) and for the period from September 4, 2002 (inception) to March 31, 2014 (unaudited)</u>                         | 6  |
| <u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>  | 7  |
| Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>   | 16 |
| Item 3. <u>Quantitative and Qualitative Disclosure About Market Risk</u>   | 25 |
| Item 4. <u>Controls and Procedures</u>   | 26 |

**PART II  
OTHER INFORMATION**

|  |    |
|--|----|
| Item 1. <u>Legal Proceedings</u>   | 27 |
| Item 1A. <u>Risk Factors</u>   | 27 |
| Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 27 |
| Item 3. <u>Defaults Upon Senior Securities</u>                             | 28 |
| Item 4. <u>Mine Safety Disclosures</u>                                     | 28 |
| Item 5. <u>Other Information</u>   | 28 |
| Item 6. <u>Exhibits</u>  | 29 |
| <u>Signatures</u>  | 29 |

Exhibit Index

30

2

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “warrant,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of obeticholic acid, or OCA, and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our product candidates;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our need for and ability to obtain additional financing;

- our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof;
- our use of the proceeds from our initial public offering in October 2012 and our follow-on public offerings of common stock in June 2013 and April 2014;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startup Act, or JOBS Act;
- our estimates regarding expenses, future revenues, capital requirements and the accuracy thereof; and
- our ability to attract and retain key scientific or management personnel.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014, particularly in Item 1.A. Risk Factors. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to the Quarterly Report on Form 10-Q with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

**PART I****Item 1. FINANCIAL STATEMENTS****INTERCEPT PHARMACEUTICALS, INC.**  
**(A Development Stage Company)****Condensed Consolidated Balance Sheets**

|  | December 31,<br>2013<br>(Audited) | March 31,<br>2014<br>(Unaudited) |
|--|-----------------------------------|----------------------------------|
| Assets   |                                   |                                  |
| Current assets:  |                                   |                                  |
| Cash and cash equivalents  | \$ 13,363,185                     | \$ 11,210,833                    |
| Investment securities, available-for-sale  | 131,468,797                       | 122,894,295                      |
| Prepaid expenses and other current assets  | 2,732,556                         | 4,796,328                        |
| Total current assets   | 147,564,538                       | 138,901,456                      |
| Fixed assets, net  | 1,672,295                         | 1,910,442                        |
| Security deposits  | 1,081,747                         | 1,082,209                        |
| Total assets   | \$ 150,318,580                    | \$ 141,894,107                   |
| Liabilities and Stockholders' Equity (Deficit)   |                                   |                                  |
| Current liabilities:   |                                   |                                  |
| Accounts payable, accrued expenses and other liabilities   | \$ 7,259,805                      | \$ 8,763,999                     |
| Short-term portion of warrant liability  | -                                 | 276,738,805                      |
| Short-term portion of deferred revenue   | 1,621,622                         | 1,621,620                        |
| Total current liabilities  | 8,881,427                         | 287,124,424                      |
| Long-term liabilities:   |                                   |                                  |
| Long-term portion of deferred revenue  | 8,918,916                         | 8,513,516                        |
| Long-term portion of warrant liability   | 50,112,137                        | -                                |
| Total liabilities  | 67,912,480                        | 295,637,940                      |
| Stockholders' equity (deficit):  |                                   |                                  |
| Common stock. 25,000,000 shares authorized; 19,389,610, and 19,566,640 shares issued and outstanding as of December 31, 2013 and March 31, 2014, respectively; par value \$0.001 per share | 19,390                            | 19,567                           |
| Additional paid-in capital   | 268,302,617                       | 289,834,694                      |
| Accumulated other comprehensive income, net  | 59,853                            | 43,484                           |
| Accumulated deficit during development stage   | (185,975,760)                     | (443,641,578)                    |



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|  |                |                |
|--|----------------|----------------|
| Total stockholders' equity (deficit)       | 82,406,100     | (153,743,833)  |
| Total liabilities and stockholders' equity | \$ 150,318,580 | \$ 141,894,107 |

See accompanying notes to the condensed consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**Condensed Consolidated Statements of Operations and Comprehensive Loss**

**(Unaudited)**

|  | Three Months Ended |                 | Period From       |
|--|--------------------|-----------------|-------------------|
|  | March 31,          |                 | September 4, 2002 |
|  | 2013               | 2014            | (Inception)       |
|  |                    |                 | Through           |
|  |                    |                 | March 31, 2014    |
| Licensing revenue                                      | \$405,405          | \$405,403       | \$ 6,278,265      |
| Costs and expenses:                                    |                    |                 |                   |
| Research and development                               | 4,832,556          | 25,929,683      | 125,305,881       |
| General and administrative                             | 2,396,854          | 5,651,127       | 48,381,048        |
| Total costs and expenses                               | 7,229,410          | 31,580,810      | 173,686,929       |
| Other income (expense):                                |                    |                 |                   |
| Revaluation of warrants                                | (3,682,505 )       | (226,626,668 )  | (278,143,310 )    |
| Foreign currency loss on liquidation                   | -                  | -               | (191,733 )        |
| Other income, net                                      | 296,362            | 136,257         | 1,613,170         |
| QTDP Grant   | -                  | -               | 488,959           |
|  | (3,386,143 )       | (226,490,411 )  | (276,232,914 )    |
| Net loss   | (10,210,148)       | (257,665,818)   | (443,641,578 )    |
| Dividends on preferred stock, not declared             | -                  | -               | (10,944,134 )     |
| Net loss attributable to common stockholders           | \$(10,210,148)     | \$(257,665,818) | \$(454,585,712 )  |
| Net loss per share, basic and diluted                  | \$(0.62 )          | \$(13.21 )      |                   |
| Weighted average shares outstanding, basic and diluted | 16,558,297         | 19,504,748      |                   |
| Other comprehensive gain (loss):                       |                    |                 |                   |
| Unrealized gain (loss) on investment securities        | (245,481 )         | 16,369          | 43,484            |
| Total comprehensive loss                               | \$(10,455,629)     | \$(257,649,449) | \$(443,598,094 )  |

See accompanying notes to the condensed consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**  
**(A Development Stage Company)**

**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

|   | Three Months Ended March 31, |                  | Period from<br>September 4,<br>2002<br>(Inception)<br>Through<br>March 31, 2014 |
|---|------------------------------|------------------|---|
|   | 2013                         | 2014             |   |
| Cash flows from operating activities:                                       |                              |                  |   |
| Net loss  | \$(10,210,148 )              | \$(257,665,818 ) | \$(443,641,578 )  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                              |                  |   |
| Revaluation of warrants   | 3,682,505                    | 226,626,668      | 278,143,310   |
| Stock-based compensation  | 1,607,181                    | 19,072,642       | 38,296,607  |
| Impairment of bonds   | -                            | -                | 151,402   |
| Loss from sale of assets  | -                            | -                | 217,296   |
| Depreciation  | 22,650                       | 61,661           | 2,534,013   |
| Foreign currency loss on liquidation  | -                            | -                | 191,733   |
| Amortization of investment premium  | -                            | 551,913          | 2,284,975   |
| Changes in:   |                              |                  |   |
| Prepaid expenses and other current assets                                   | 187,568                      | (2,064,234 )     | (5,137,984 )  |
| Accounts payable, accrued expenses, and other current liabilities           | (520,024 )                   | 1,504,194        | 8,764,003   |
| Deferred revenue  | (405,405 )                   | (405,402 )       | 10,135,136  |
| Interest accrued on promissory notes  | -                            | -                | 91,249  |
| Net cash used in operating activities                                       | (5,635,673 )                 | (12,318,376 )    | (107,969,838 )  |
| Cash flows from investing activities:                                       |                              |                  |   |
| Investments in certificates of deposit                                      | -                            | -                | (627,631 )  |
| Purchases of investment securities  | (10,243,468 )                | (15,723,676 )    | (207,489,760 )  |
| Sales of investment securities  | 2,000,000                    | 23,729,896       | 82,089,650  |
| Purchases of equipment, improvements, and furniture and fixtures            | (8,664 )                     | (299,808 )       | (3,326,186 )  |
| Net cash (used in) provided by investing activities                         | (8,252,132 )                 | 7,706,412        | (129,353,927 )  |
| Cash flows from financing activities:                                       |                              |                  |   |
| Proceeds from issuance of stock offerings, net of issuance costs            | -                            | -                | 233,646,499   |
| Proceeds from issuance of common stock warrants                             | -                            | -                | 7,385,897   |
| Costs associated with issuance of stock                                     | -                            | (338,816 )       | (338,816 )  |

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|  |               |              |              |
|--|---------------|--------------|--------------|
| Payments of capital lease obligation   | -             | -            | (1,335,567 ) |
| Proceeds from exercise of options  | 87,428        | 2,798,428    | 7,735,221    |
| Proceeds from exercise of warrants   | -             | -            | 383,097      |
| Proceeds from issuance of convertible promissory notes payable                                   | -             | -            | 1,250,000    |
| Net cash provided by financing activities  | 87,428        | 2,459,612    | 248,726,331  |
| Effect of exchange rate changes  | -             | -            | (191,733 )   |
| Net (decrease) in cash and cash equivalents  | (13,800,377 ) | (2,152,352 ) | 11,210,833   |
| Cash and cash equivalents – beginning of period  | 45,511,641    | 13,363,185   | -            |
| Cash and cash equivalents – end of period  | \$31,711,264  | \$11,210,833 | \$11,210,833 |
| Supplemental disclosure of cash flow information:  |               |              |              |
| Cash paid during the year for interest   | \$-           | \$-          | \$181,980    |
| Supplemental disclosures of noncash activities:  |               |              |              |
| Conversion of promissory note payable, including accrued interest of \$91,250 into common shares | \$-           | \$-          | \$1,341,249  |
| Issuance of 108,169 warrants for private placement agent fees                                    | -             | -            | 1,471,485    |
| Acquisition of equipment pursuant to capital leases  | -             | -            | 1,335,567    |
| Issuance of common stock for cashless warrant exchange   | 3,628,077     | -            | 9,713,800    |

See accompanying notes to the condensed consolidated financial statements.

## Notes to Condensed Consolidated Financial Statements (unaudited)

### 1. Nature of Business and Basis of Presentation

Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”), a development stage company, is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver and intestinal diseases utilizing its proprietary bile acid chemistry. The Company’s product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

The Company has its administrative headquarters in New York, New York and an office in San Diego, California. The Company has a wholly owned subsidiary in Italy which acts as the Company’s legal representative for its clinical trials in the European Union to satisfy European Union regulatory requirements. Intercept was incorporated in Delaware in September 2002.

The Company’s condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying condensed interim financial statements are unaudited. The condensed interim unaudited financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company’s financial position, results of operations and cash flows for the dates and periods presented herein. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes set forth in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014. The results for the three months ended March 31, 2013 and March 31, 2014 (unaudited), and for the period from inception (September 4, 2002) through March 31, 2014 (unaudited) are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods or any future year or period.

### 2. Significant Agreements

*Dainippon Sumitomo Pharma Co, Ltd. (DSP)*

In March 2011, the Company entered into an exclusive license agreement with DSP to research, develop and commercialize obeticholic acid (OCA) as a therapeutic for the treatment of primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH) in Japan and China (excluding Taiwan) and agreed not to commercialize other farnesoid X receptor, or FXR, agonist compounds or products for PBC, NASH or specified additional indications in countries in which DSP retains an exclusive license to OCA under the agreement. Under the terms of the license agreement, the Company received an up-front payment from DSP of \$15.0 million and may be eligible to receive additional milestone payments up to an aggregate of approximately \$30.0 million in development milestones based on the initiation or completion of clinical trials, \$70.0 million in regulatory approval milestones and \$200.0 million in sales milestones. The regulatory approval milestones include \$15.0 million for receiving marketing approval for OCA for NASH in Japan, \$10.0 million for receiving marketing approval for OCA for NASH in China, and up to \$5.0 million for receiving marketing approval for OCA for PBC in the United States. The sales milestones are based on aggregate sales amounts of OCA and include \$5.0 million for achieving net sales of \$50.0 million, \$10.0 million for achieving net sales of \$100.0 million, \$20.0 million for achieving net sales of \$200.0 million, \$40.0 million for achieving net sales of \$400.0 million and \$120.0 million for achieving net sales of \$1.2 billion. DSP is also required to make royalty payments ranging from the tens to the twenties in percent based on net sales of OCA products in the DSP territory. DSP has the exclusive option to add several other Asian countries to its territory, including Korea and Taiwan, and to pursue OCA for additional indications. DSP will be responsible for the costs of developing and commercializing OCA in its territory.

The Company evaluated the license agreement with DSP and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this license include an exclusive license to its technology, technical and scientific support to the development plan and participation on a joint steering committee. The Company determined that these performance obligations represent a single unit of accounting, since, initially, the license does not have stand-alone value to DSP without the Company's technical expertise and steering committee participation during the development of OCA. This development period is currently estimated as continuing through June 2020 and, as such, the up-front payment is being recognized ratably over this period. During the three months ended March 31, 2013 and 2014, the Company recorded revenue of \$405,000 and \$405,000, respectively, in "Licensing Revenue" in its Consolidated Statement of Operations for the Company's efforts under the agreement. The Company has not achieved any of the milestones relating to the agreement as of March 31, 2014 and has not recognized any revenue related to such milestones. The Company has determined that each potential future development, regulatory and sales milestone is substantive.

**3. Investments**

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2013 and March 31, 2014:

|  | As of December 31, 2013 |          |            |           |
|--|-------------------------|----------|------------|-----------|
|  | Gross                   |          | Gross      |           |
|  | Amortized Cost          | Realized | Unrealized | Fair      |
|  | Gains                   | Losses   | Losses     | Value     |
|  | (In thousands)          |          |            |           |
| Cash and cash equivalents:                   |                         |          |            |           |
| Cash and money market funds                  | \$13,363                | \$ -     | \$ -       | \$13,363  |
| Investment securities:                       |                         |          |            |           |
| Commercial paper                             | 7,993                   | 1        | -          | 7,994     |
| Corporate debt securities                    | 115,704                 | 115      | (59 )      | 115,760   |
| U.S. government and agency securities        | 6,657                   | 6        | -          | 6,663     |
| Municipal securities                         | 1,051                   | 1        | -          | 1,052     |
| Total investments                            | 131,405                 | 123      | (59 )      | 131,469   |
| Total cash, cash equivalents and investments | \$144,768               | \$ 123   | \$ (59 )   | \$144,832 |

|  | As of March 31, 2014 |          |            |           |
|--|----------------------|----------|------------|-----------|
|  | Gross                |          | Gross      |           |
|  | Amortized Cost       | Realized | Unrealized | Fair      |
|  | Gains                | Losses   | Losses     | Value     |
|  | (In thousands)       |          |            |           |
| Cash and cash equivalents:                   |                      |          |            |           |
| Cash and money market funds                  | \$11,211             | \$ -     | \$ -       | \$11,211  |
| Investment securities:                       |                      |          |            |           |
| Commercial paper                             | 2,996                | 1        | -          | 2,997     |
| Corporate debt securities                    | 112,185              | 101      | (63 )      | 112,223   |
| U.S. government and agency securities        | 6,626                | 5        | -          | 6,631     |
| Municipal securities                         | 1,039                | 4        | -          | 1,043     |
| Total investments                            | 122,846              | 111      | (63 )      | 122,894   |
| Total cash, cash equivalents and investments | \$134,057            | \$ 111   | \$ (63 )   | \$134,105 |

The following table shows the gross unrealized losses and fair value of the Company's available-for-sale investments aggregated by investment category and length of time that individual securities have been in the position:

|                           | As of December 31, 2013 |                         |  |                         |            |                         |   |
|---------------------------|-------------------------|-------------------------|--|-------------------------|------------|-------------------------|---|
|                           | Less than 12 months     |                         | 12 Months or greater<br>(In thousands) |                         | Total      |                         |   |
|                           | Fair Value              | Gross Unrealized Losses | Fair Value                             | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses |   |
| Corporate debt securities | \$9,515                 | \$(2                    | ) \$31,312                             | \$(57                   | ) \$40,827 | \$(59                   | ) |
| Total                     | \$9,515                 | \$(2                    | ) \$31,312                             | \$(57                   | ) \$40,827 | \$(59                   | ) |

|                           | As of March 31, 2014 |                         |  |                         |            |                         |   |
|---------------------------|----------------------|-------------------------|--|-------------------------|------------|-------------------------|---|
|                           | Less than 12 months  |                         | 12 Months or greater<br>(In thousands) |                         | Total      |                         |   |
|                           | Fair Value           | Gross Unrealized Losses | Fair Value                             | Gross Unrealized Losses | Fair Value | Gross Unrealized Losses |   |
| Corporate debt securities | \$15,759             | \$ (13                  | ) \$32,234                             | \$ (50                  | ) \$47,993 | \$ (63                  | ) |
| Total                     | \$15,759             | \$ (13                  | ) \$32,234                             | \$ (50                  | ) \$47,993 | \$ (63                  | ) |

#### 4. Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is established against net deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be resolved. The effect of a change in tax rates or laws on deferred tax assets and deferred tax liabilities is recognized in operations in the period that includes the enactment date of the rate change.

The deferred tax asset or liability represents future tax return consequences of those differences, which will be taxable when the assets and liabilities are recovered or settled. The provision for income taxes may differ from the actual



expense that would result from applying the federal statutory rate to income before taxes because certain expenses for financial reporting purposes are not deductible for tax purposes. At December 31, 2013 and March 31, 2014, the Company had available net operating loss carryforwards to reduce future taxable income of approximately \$108.2 million and \$123.4 million, respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2032. The ability of the Company to utilize its net operating losses in future years is subject to limitation in accordance with provisions of Section 382 of the Internal Revenue Code due to previous ownership changes; however, these changes have not resulted in material limitations to the Company's ability to utilize the net operating losses. The Company's combined federal, state and city deferred tax asset of approximately \$60.2 million and \$74.5 million at December 31, 2013 and March 31, 2014, respectively, resulted from the tax effects of net operating losses and differences between the book and tax bases for the share-based compensation and depreciation. The Company does not have any deferred tax liabilities. Since the Company has not yet achieved sustained profitable operations, management believes its deferred tax assets do not satisfy the more-likely-than-not realization criteria and has provided an allowance for the full amount of the tax asset. As a result, the Company has not recorded any income tax benefit since its inception.

## 5. Warrants to Purchase Common Stock

In conjunction with various financing transactions, the Company issued warrants to purchase the Company's common stock. Certain of the warrants include a so-called "down round" provision that provides for a reduction in the warrant exercise price if there are subsequent issuances of additional shares of common stock for consideration per share less than the per share warrant exercise prices and the remaining warrants contain a provision that require the underlying shares to be registered upon an IPO. These warrants are deemed to be derivative instruments and as such, are recorded as a liability and are marked-to-market at each reporting period. The Company estimates the fair values of the warrants at each reporting period using a Black-Scholes option-pricing model. Management concluded, under the Company's facts and circumstances, that the estimated fair values of the warrants using the Black-Scholes option-pricing model approximates, in all material respects, estimates the values determined using a binomial valuation model. The estimates in the Black-Scholes option-pricing model and the binomial valuation model are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. Changes in the fair value of the common stock warrant liability from the prior period are recorded as a component of other income and expense.

As of March 31, 2014, the Company had outstanding warrants to purchase a total of 865,381 shares of its common stock, at a weighted average exercise price of \$10.40 per share. These warrants were exercised on a cashless basis on April 10, 2014 into 834,758 shares of the Company's common stock. The Company will reduce the warrant value to \$220.9 million, reclassify such value to equity in the second quarter of 2014 and will record a final non-cash warrant revaluation adjustment to other income of approximately \$56 million.

## 6. Fair Value Measurements

The carrying amounts of the Company's receivables and payables approximate their fair value due to their short maturities.

Accounting principles provide guidance for using fair value to measure assets and liabilities. The guidance includes a three level hierarchy of valuation techniques used to measure fair value, defined as follows:

**Unadjusted Quoted Prices** — The fair value of an asset or liability is based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1).

**Pricing Models with Significant Observable Inputs** — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).

Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

The Company considers an active market as one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. Conversely, the Company views an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. When appropriate, non-performance risk, or that of a counterparty, is considered in determining the fair values of liabilities and assets, respectively.

The Company's cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Investments are classified as Level 2 instruments based on market pricing or other observable inputs. None of the Company's investments are classified within Level 3 of the fair value hierarchy. The Company's warrant liability has been valued pursuant to the discussion in note 5 above and thus is included in Level 3.

Financial assets and liabilities, carried at fair value are classified in the tables below in one of the three categories described above:

|                                       | Total        | Fair Value Measurements Using  |   |  |
|---------------------------------------|--------------|--|---|--|
|                                       |              | Quoted<br>Prices<br>in<br>Active<br>Markets<br>for<br>Identical<br>Assets<br>or<br>Liabilities<br>(Level<br>1)<br>(In thousands) | Significant<br>Other<br>Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| December 31, 2013                     |              |  |   |  |
| Assets:                               |              |  |   |  |
| Money market funds                    | \$8,216      | \$8,216  | \$ —  | \$ —   |
| Available for sale securities:        |              |  |   |  |
| Commercial paper                      | 7,994        | —  | 7,994   | \$ —   |
| Corporate debt securities             | 115,760      | —  | 115,760   | —  |
| U.S. government and agency securities | 6,663        | —  | 6,663   | —  |
| Municipal securities                  | 1,052        | —  | 1,052   | —  |
| Total assets:                         | \$139,685    | \$8,216  | \$ 131,469  | \$ —   |
| Liabilities:                          |              |  |   |  |
| Warrants to purchase common stock     | \$(50,112 )  | \$—  | \$ —  | \$( 50,112 )                                       |
| Total liabilities                     | \$(50,112 )  | \$—  | \$ —  | \$( 50,112 )                                       |
| March 31, 2014                        |              |  |   |  |
| Assets:                               |              |  |   |  |
| Money market funds                    | \$7,052      | \$7,052  | \$ —  | \$ —   |
| Available for sale securities:        |              |  |   |  |
| Commercial paper                      | 2,997        | —  | 2,997   | —  |
| Corporate debt securities             | 112,223      | —  | 112,223   | —  |
| U.S. government and agency securities | 6,631        | —  | 6,631   | —  |
| Municipal securities                  | 1,043        | —  | 1,043   | —  |
| Total assets:                         | \$129,946    | \$7,052  | \$ 122,894  | \$ —   |
| Liabilities:                          |              |  |   |  |
| Warrants to purchase common stock     | \$(276,739 ) | \$—  | \$ —  | \$( 276,739 )                                      |
| Total liabilities                     | \$(276,739 ) | \$—  | \$ —  | \$( 276,739 )                                      |



The estimated fair value of marketable debt securities (commercial paper, corporate debt securities, U.S. government and agency securities and municipal securities), by contractual maturity, are as follows:

|                                      | Fair Value as of |           |
|--------------------------------------|------------------|-----------|
|                                      | December         | March     |
|                                      | 31, 2013         | 31, 2014  |
|                                      | (In thousands)   |           |
| Due in one year or less              | \$56,044         | \$67,967  |
| Due after one year through 2 years   | 75,425           | 54,927    |
| Total investments in debt securities | \$131,469        | \$122,894 |

Actual maturities may differ from contractual maturities because issuers may have the right to call or prepay obligations without call or prepayment penalties.

## 7. Stockholders' Equity and Preferred Stock

### *Common Stock*

In September 2002, the Company issued 949,035 shares of common stock at a price of \$0.03 per share to the founders of the Company (Founders' shares).

In November 2002, the Company issued 60,576 shares of common stock at a price of \$0.03 per share to the principal investigators and other researchers of the Company pursuant to an authorization by the Board of Directors to issue and sell these shares by subscription to the named parties in conjunction with the signing of certain research agreements.

In October 2003, the Company issued 112,498 shares of common stock at a price of \$0.03 per share to the two principal investigators pursuant to an authorization by the Board of Directors to issue and sell these shares by subscription.

In October 2003, the Company repurchased and canceled 550,960 Founders' shares from certain founders of the Company at a price of \$0.03 per share.

From October 2003 through May 2004, pursuant to a private placement agreement dated October 2003, the Company issued an aggregate of 392,163 shares of common stock at a price of \$7.22 per share, receiving net proceeds of \$2.4 million after \$474,000 in related offering costs. In addition, Class A warrants to purchase 137,251 shares of common stock and Class B warrants to purchase 117,640 shares of common stock were issued to the placement agent and its assigns as additional placement agent commission under the terms of the placement agent agreement.

In November 2005, the Company issued 51,922 shares of common stock, warrants with a two-year term to purchase 51,922 shares of common stock at an exercise price of \$7.22 per share and warrants with a five-year term to purchase 86,538 shares of common stock at an exercise price of \$7.22 per share, all pursuant to a private subscription agreement with two outside investors, receiving net proceeds of \$375,000.

In May 2006, pursuant to a private placement agreement, the Company issued 2,087,091 shares of common stock at a price of \$9.82, receiving net proceeds of \$19.5 million, after \$1.0 million in related offering costs. Also in May 2006, the Company's 6% convertible promissory notes that were issued in February 2005 with a face amount of \$1.3 million, along with \$91,000 of accrued interest, were converted into 160,637 shares of common stock at a price of \$8.35 per share pursuant to the mandatory conversion terms of the notes.

In October 2012, the Company completed the initial public offering (IPO) of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 5,750,000 shares of common stock under the registration statement at a public offering price of \$15.00 per share. Net proceeds were approximately \$78.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's preferred stock (described below) were converted into 7,403,817 shares of common stock. Additionally, upon completion of the IPO, the Company is now authorized to issue 25,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share.

In June 2013, the Company completed a public offering of 1,989,500 shares of its common stock at a public offering price of \$33.01 per share. The shares were registered pursuant to a registration statement on Form S-1. Net proceeds were approximately \$61.2 million, after deducting underwriting discounts and commission and offering expenses payable by the Company.

In April 2014, the Company completed a public offering of 1,000,000 shares of its common stock, of which 600,000 shares were sold by the Company and 400,000 shares were sold by certain selling stockholders, at a public offering price of \$320.00 per share. The shares were registered pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and estimated offering expenses, the Company received net proceeds from the offering of approximately \$183.4 million. The Company did not receive any proceeds from the sale of shares of common stock by the selling stockholders.

#### *Dividends*

The holders of common stock are entitled to receive dividends from time to time as declared by the Board of Directors. No cash dividend may be declared or paid to common stockholders until paid on each series of outstanding preferred stock in accordance with their respective terms.

#### *Voting*

The holders of shares of common stock are entitled to one vote for each share held with respect to all matters voted on by the stockholders of the Company.

#### *Preferred Stock*

In May 2008, to effectuate the sale of Series A preferred stock, the Company amended and restated its Certificate of Incorporation in its entirety to increase the number of shares of preferred stock it was authorized to issue to 13,888,889 shares and to designate such shares as Series A preferred stock. In May 2008, 13,888,889 shares of Series A preferred stock were sold to Genextra, S.p.A. for net proceeds of \$24.3 million, after \$749,000 in related offering costs. In connection with this financing, the Company issued warrants with a five-year term to purchase 108,169 shares of common stock at \$10.40 per share to the placement agent.



In January 2010, the Company further amended and restated its Certificate of Incorporation in its entirety to increase the number of shares of preferred stock it was authorized to issue to 27,777,778 shares and designated 13,888,889 of such shares as Series B preferred stock. In January 2010, 13,888,889 shares of Series B preferred stock and a warrant with a five-year term to purchase 865,381 shares of common stock at \$10.40 per share were sold to Genextra for \$24.9 million, after \$112,000 in related offering costs.

In August 2012, the Company further amended and restated its Certificate of Incorporation in its entirety to increase the number of shares of preferred stock it was authorized to issue to 52,777,778 shares and designated 25,000,000 of such shares as Series C preferred stock. In August 2012, 15,000,000 shares of Series C preferred stock were sold to Genextra and OrbiMed Advisors LLC for \$29.7 million, after \$300,000 in related offering costs. Upon the completion of the IPO, all outstanding shares of the Company's preferred stock, including 13,888,889 shares of Series A preferred stock, 13,888,889 shares of Series B preferred stock and 15,000,000 shares of Series C preferred stock, were converted into 7,403,817 shares of common stock and all accrued dividends on the preferred stock were eliminated.

### **8.2003 Stock Incentive Plan and 2012 Stock Plan**

The 2003 Stock Incentive Plan was terminated upon the pricing of the IPO in October 2012, and 555,843 shares available under the 2003 Stock Incentive Plan were added to the 2012 Plan. All outstanding options issued under the 2003 Plan as of the date of termination remained outstanding and are subject to their respective terms and the terms of the 2003 Plan.

In September 2012, the Company's board of directors and stockholders approved the 2012 Equity Incentive Plan (2012 Plan), which became effective upon the pricing of the Company's IPO in October 2012. The 2012 Plan will expire on September 13, 2022. Under the 2012 Plan, the Company may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. As of March 31, 2014, there were 1,066,627 shares of common stock authorized for issuance under the 2012 Plan (including 775,584 shares of common stock which were added to the 2012 Plan on January 1, 2014 in accordance with its terms).

The following table summarizes stock option activity during the three months ended March 31, 2014:

|                                | Number of<br>Shares | Weighted<br>Average<br>Exercise Price |
|--------------------------------|---------------------|---------------------------------------|
| Outstanding, December 31, 2013 | 1,524,837           | \$ 21.33                              |
| Granted                        | 121,900             | 251.55                                |
| Exercised                      | (160,902 )          | 16.62                                 |
| Forfeited                      | (3,029 )            | 21.50                                 |
| Outstanding, March 31, 2014    | 1,482,806           | \$ 40.76                              |
| Exercisable, March 31, 2014    | 760,752             | \$ 12.62                              |

The following table summarizes the aggregate restricted stock unit (RSU) activity:

|                                | Number of<br>Shares | Weighted<br>Average<br>Grant<br>Date Fair<br>Value |
|--------------------------------|---------------------|--|
| Outstanding, December 31, 2013 | 121,069             | \$ 25.30   |
| Exercised                      | (16,128 )           | 25.50  |
| Outstanding, March 31, 2014    | 104,941             | \$ 25.26   |

### 9. Net Loss Per Share

The following table presents the historical computation of basic and diluted net loss per share:

|  | Three Months<br>Ended March 31,<br>2013                      2014<br>(In thousands, except share<br>and<br>per share amounts) |              |
|--|---|--------------|
| Historical net loss per share                |   |              |
| Numerator:                                   |   |              |
| Net loss attributable to common stockholders | \$(10,210 )   | \$(257,666 ) |

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Denominator:

|  |            |            |
|--|------------|------------|
| Weighted average shares outstanding, basic and diluted | 16,558,297 | 19,504,748 |
| Net loss per share, basic and diluted                  | \$(0.62    | ) \$(13.21 |

14

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding:

|                                   | As of March 31, |       |
|-----------------------------------|-----------------|-------|
|                                   | 2013            | 2014  |
|                                   | (In thousands)  |       |
| Options                           | 1,646           | 1,483 |
| Warrants to purchase common stock | 1,043           | 865   |
| Restricted stock units            | 176             | 105   |
| Total                             | 2,865           | 2,453 |

## 10. Litigation

On February 21, 2014 and February 28, 2014, purported shareholder class actions, styled *Scot H. Atwood v. Intercept Pharmaceuticals, Inc. et al.* and *George Burton v. Intercept Pharmaceuticals, Inc. et al.*, respectively, were filed in the United States District Court for the Southern District of New York, naming the Company and certain of its officers as defendants. These lawsuits were filed by stockholders who claim to be suing on behalf of anyone who purchased or otherwise acquired the Company's securities between January 9, 2014 and January 10, 2014.

The lawsuits allege that the Company made material misrepresentations and/or omissions of material fact in its public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to the Company's January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. The plaintiffs in each suit seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees. On April 22, 2014, two individuals each moved to consolidate the cases and to be appointed as the lead plaintiff. Those motions are currently pending before the Court.

Additional complaints may be filed against the Company and its directors and officers related to its disclosures.

The Company believes that these lawsuits are without merit. At this time, no assessment can be made as to the likely outcome of these lawsuits or whether the outcome will be material to the Company. Therefore, the Company has not accrued for any loss contingencies related to these lawsuits.

## 11. Subsequent Events

### *New San Diego Office Lease*

On May 1, 2014, the Company entered into a lease agreement with The Irvine Company LLC for its new office in San Diego. The lease will provide the Company with approximately 47,000 rentable square feet in San Diego for office space. The lease term is anticipated to commence in September 2014 and is anticipated to end in September 2019. The Company also has an option to further extend the lease for an additional five year term at market rates prevailing at such time.

The rent for the first year will be approximately \$874,000 without giving effect to rent abatements and the rent will gradually increase every 12 months during the lease term. During the first six months, the Company will receive a partial rent abatement from the landlord. The landlord will also provide the Company with contributions of up to approximately \$2.4 million for improvements to the office space.

Pursuant to the terms of the new lease, the Company has provided the landlord with a letter of credit for \$874,000, which will decrease at certain times during the term of the lease.

The Irvine Company LLC, which is also the landlord of the Company's current San Diego office, has agreed to release the Company from its obligations under the current San Diego lease effective as of the commencement date of the lease for the new San Diego office.

## 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 together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2013 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver and intestinal diseases with high unmet need utilizing our proprietary bile acid chemistry. Our product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog, or a chemical substance that has a structure based on a naturally occurring human bile acid. OCA is a first-in-class product candidate that selectively binds to and induces activity in the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for primary biliary cirrhosis, or PBC, as a second line treatment for patients who have an inadequate response to or who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. In March 2014, we completed a Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, that we anticipate will serve as the basis for seeking the first regulatory approval to market OCA in the United States and Europe. We expect to complete our filings for marketing approval of OCA in PBC in the United States and Europe during the first half of 2015. We also anticipate finalizing the protocol for our clinical outcomes confirmatory trial in PBC during the third quarter of 2014 and initiating the trial around year end 2014.

OCA is also currently being evaluated in a Phase 2b trial for the treatment of nonalcoholic steatohepatitis, or NASH, known as the FLINT trial, which has been sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. In January 2014, the NIDDK stopped the double-blind treatment phase of the FLINT trial early following a planned interim analysis showing that OCA had met the primary efficacy endpoint of the trial based on a pre-defined interim efficacy criteria. The NIDDK's decision to stop the FLINT treatment phase early was based primarily on OCA having met the efficacy criterion, while also being

informed by the risks involved in continuing to perform liver biopsies in the remaining patients and the available safety data from the trial.

In addition to PBC and NASH, we are developing OCA in other patient populations, including cirrhosis, primary sclerosing cholangitis, or PSC, portal hypertension, alcoholic hepatitis and bile acid diarrhea and anticipate initiating clinical trials for several of these indications throughout 2014. Furthermore, we plan to complete IND-enabling studies in INT-767, an earlier stage product for which we plan to initiate a Phase 1 trial in the first half of 2015. OCA has received orphan drug designation in the United States and Europe for the treatment of PBC and PSC. We own worldwide rights to OCA outside of Japan and China, where we have exclusively licensed the compound to Dainippon Sumitomo Pharma, or DSP, and granted it an option to exclusively license OCA in certain other Asian countries.

In April 2014, we completed a follow-on public offering of 1,000,000 shares of our common stock, of which 600,000 shares were sold by us and 400,000 shares were sold by certain selling stockholders, at a public offering price of \$320.00 per share. After underwriting discounts and commissions and estimated offering expenses, we received net proceeds from the offering of approximately \$183.4 million. We did not receive any proceeds from the sale of shares of common stock by the selling stockholders. Our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol "ICPT."

We have incurred net losses in each year since our inception in 2002. Our net losses were approximately \$10.2 million and \$257.7 million for the three months ended March 31, 2013 and 2014, respectively. As of March 31, 2014, we had an accumulated deficit of approximately \$443.6 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs, general and administrative costs associated with our operations and the mark-to-market of our liability-classified warrants.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

• complete the development of our lead product candidate, OCA, for the treatment of PBC, NASH, and other patient populations;

• seek to obtain regulatory approvals for OCA for PBC, NASH and other potential patient populations;

• outsource the commercial manufacturing of OCA for any indications for which we receive regulatory approval;

• engage in activities relating to the sales, marketing and distribution of OCA for any indications for which we may receive regulatory approval;

• continue research and development efforts with our preclinical development compounds, such as INT-767, whether independently or with a third-party collaborator;

• maintain, expand and protect our intellectual property portfolio;

• add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and

• operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to the commercialization of OCA or any of our other product candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

We have our administrative headquarters in New York, New York and an office in San Diego, California. We have a wholly owned subsidiary in Italy which acts as our legal representative for our clinical trials in the European Union to satisfy European Union regulatory requirements.

## Recent Developments



*Primary Endpoint Met in Phase 3 POISE Trial of OCA in PBC*

In March 2014, we announced that the primary endpoint was achieved in our international Phase 3 POISE trial studying the safety and efficacy of a once-daily treatment with OCA in PBC patients with an inadequate therapeutic response to, or who are unable to tolerate, ursodiol. There were 217 patients randomized to one of three groups in the trial: placebo, 10 mg OCA or 5 mg OCA for six months titrated to 10 mg OCA based on clinical response. Of the 198 patients who completed the double-blind phase, more than 95% continued in the long term safety extension, or LTSE, phase of the trial.

The POISE data showed that OCA, at both a 10 mg dose and a 5 mg dose titrated to 10 mg, met the trial's primary endpoint of achieving a reduction in serum alkaline phosphatase, or ALP, to below a threshold of 1.67 times upper limit normal, with a minimum of 15% reduction in ALP level from baseline, and a normal bilirubin level after 12 months of therapy. Patients with ALP and bilirubin levels below the thresholds set forth in the POISE trial primary endpoint have been shown in long-term clinical studies to have a significantly lower risk of progressing to liver transplant and death. The proportion of patients meeting the POISE trial primary endpoint was 10% in the placebo group, 47% in the 10 mg OCA group and 46% in the OCA titration group (both dose groups  $p < 0.0001$  as compared to placebo) in an intention-to-treat analysis. The placebo group experienced a mean decrease in ALP from baseline of 5%, compared to a significant mean decrease of 39% in the 10 mg OCA dose group and 33% in the OCA titration group (both dose groups  $p < 0.0001$  as compared to placebo). OCA treated patients achieved highly statistically significant reductions in ALP beginning as early as two weeks after initiation of treatment, with a peak effect achieved by six months.

In addition, both OCA dose groups met pre-specified secondary endpoints of improving other clinically relevant liver enzymes. Reductions in gamma-glutamyl transferase, or GGT, of 64% in the 10 mg OCA dose group and 50% in the OCA titration group, alanine transaminase, or ALT, of 42% in the 10 mg OCA dose group and 36% in the OCA titration group, and aspartate transaminase, or AST, of 24% in the 10 mg OCA dose group and 22% in the OCA titration group, were observed, respectively (both OCA dose groups  $p < 0.0005$  as compared to placebo). PBC patients typically have significantly elevated HDL cholesterol levels and modest decreases in HDL were observed in both OCA dose groups, similar to those seen in the prior PBC clinical trials. In addition, modest but significant decreases in triglycerides, VLDL cholesterol and HDL cholesterol, but no change in LDL cholesterol were observed in the OCA dose groups.

Pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group. Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and only one (1%) patient was in the OCA titration group (in a patient who had titrated up to 10 mg). The incidence and severity of OCA-related pruritus in POISE diminished with time on therapy. Specifically, pruritus scores were no different from placebo in both OCA treatment groups during the second half of the trial.

Apart from pruritus, the incidence of adverse events was generally similar across both OCA and placebo groups (placebo: 90%, OCA 10 mg: 86%, OCA titration: 89%). Overall, serious adverse events, or SAEs, occurred in 22 (10%) of the patients and, although there were more SAEs in the OCA treatment groups, none were considered drug-related and there were no apparent patterns in the SAEs.

## **Financial Overview**

### *Revenue*

To date, we have not generated any revenue from the sale of products. All our revenue has been derived from our collaborative agreements for the development and commercialization of certain of our product candidates. In March 2011, we entered into an exclusive licensing agreement with DSP for the development of OCA in Japan and China. Under the terms of the agreement, we received an up-front payment of \$15.0 million and may be eligible to receive up to approximately \$300 million in additional payments for development, regulatory and commercial sales milestones for OCA in Japan and China. For accounting purposes, the up-front payment is recorded as deferred revenue and amortized over time. Through March 31, 2014, we recognized \$6.3 million in license revenue for amortization of up-front payments. We anticipate that we will recognize revenue of approximately \$1.6 million per year through 2020, the expected end of the development period, for the amortization of the up-front payment from DSP.

In the future, we may generate revenue from a combination of license fees and other upfront payments, research and development payments, milestone payments, product sales and royalties in connection with strategic alliances. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized by us or our strategic alliance partners. If our strategic alliance partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

***Research and Development Expenses***

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions;
- fees paid to consultants and clinical research organizations, or CROs, including in connection with our preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials;
- depreciation of leasehold improvements, laboratory equipment and computers;
- costs related to compliance with regulatory requirements; and
- costs related to stock options or other stock-based compensation granted to personnel in research and development functions.

From inception through March 31, 2014, we have incurred approximately \$125.3 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of OCA for the treatment of PBC, NASH and PSC, and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

The table below summarizes our direct research and development expenses by program for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. We have been developing OCA and other FXR agonists, as well as TGR5 agonists, and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate salaries, stock-based compensation, employee benefit or other indirect costs related to our research and development function to specific product candidates. Those expenses are included in “Personnel costs” and “Indirect research and development expense” in the table below.

|   | Three Months<br>Ended March 31, |          |
|---|---------------------------------|----------|
|   | 2013                            | 2014     |
|   | (In thousands)                  |          |
| Direct research and development expense by program: |                                 |          |
| OCA   | \$2,845                         | \$5,009  |
| INT-767   | 85                              | 584      |
| INT-777   | 44                              | -        |
| Total direct research and development expense       | 2,974                           | 5,593    |
| Personnel costs (1)                                 | 1,728                           | 19,645   |
| Indirect research and development expense           | 130                             | 692      |
| Total research and development expense              | \$4,832                         | \$25,930 |

Personnel costs include stock options and restricted stock units granted to employees and non-employees with an (1) associated stock-based compensation expense of \$709,000 and \$17.6 million for the three months ended March 31, 2013 and 2014, respectively.

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration, or FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

## *OCA*

The majority of our research and development resources are focused on our ongoing and planned clinical and preclinical studies and the other work we plan to undertake to support our New Drug Application, or NDA, and Marketing Authorization Application, or MAA, filings for OCA for the treatment of PBC, which we currently plan to complete by the first half of 2015. We have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

We completed our Phase 3 POISE trial of OCA in patients with PBC in March 2014 and expect to continue the LTSE phase of the trial through 2019.

We are currently in discussions with the FDA on the clinical outcomes trial for OCA in PBC that must be underway at the time the FDA makes a decision whether to grant accelerated approval. The clinical outcomes trial will be completed on a post-marketing basis. We currently anticipate finalizing the protocol for this trial during the third quarter of 2014 and initiating this trial around year end 2014.

We plan to conduct a Phase 1 clinical trial in healthy volunteers to evaluate the effect of OCA on the heart's electrical cycle, known as the QT interval, and additional Phase 1 clinical trials in 2014.

We have contracted with third-party manufacturers to produce the quantities of OCA needed for regulatory approval as well as the necessary supplies for our other contemplated trials and are working to secure second manufacturers.

We are currently reviewing potential third-party manufacturers for our commercial supply of OCA and plan to begin building commercial supplies, including supplies of the starting material for manufacturing OCA, in 2014.

We have contracted with and plan to engage a number of consultants in relation to our seeking of regulatory approval and intend to implement various electronic software and systems in relation to our regulatory activities.

In addition, we are evaluating OCA in other chronic liver and other intestinal diseases. Pending our detailed review of the FLINT trial results and discussions with the FDA and European Medicines Agency, or EMA, we plan to initiate our Phase 3 clinical program in NASH during the first half of 2015. In the meantime, we intend to initiate a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients in the second half of 2014 and are evaluating whether to initiate a Phase 2 trial of OCA in pediatric NASH patients in late 2014. For PSC, we intend to initiate a Phase 2 clinical trial at the end of 2014.

## *INT-767 and INT-777*

We are currently conducting research in collaboration with Servier to discover and develop additional novel TGR5 agonists. We also intend to continue to develop INT-767 (a dual FXR/TGR5 agonist) and INT-777 (pure TGR5 agonist), our two existing compounds not included in this collaboration. Currently, we plan to continue with preclinical development of INT-767 through to the filing of an Investigational New Drug, or IND, application and, subject to the IND application becoming effective, initiate a Phase 1 trial of INT-767 in healthy volunteers in the first half of 2015. We intend to continue development of INT-777 through potential collaborations with third parties over the next several years.

Other than OCA, our product development programs are at an early stage, and successful development of OCA and our future product candidates from these programs is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to our ability to maintain or enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, as well as ongoing assessments as to each future product candidate's commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance our various programs.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs for employees in executive, operational, finance and human resources functions. Other significant general and administrative expenses include OCA pre-commercial activities, facilities costs, accounting and legal services, directors and officer liability insurance, information technology, professional fees for directors, travel, and other expense of operating as a public company.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and due to the potential commercialization of our product candidates. We believe that these increases will likely include increased costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We have also incurred and may continue to incur increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies. In 2014, we anticipate that we will also implement a number of software, systems and other infrastructural changes in relation to our operations as a public company.

*Other Income, Net*

Other income consists of interest income earned on our cash, cash equivalents and investment securities. We expect interest income to increase in future periods as we invest the proceeds from our equity financings.

*Revaluation of Warrants*

In conjunction with various financing transactions, we issued warrants to purchase shares of our common stock. As of March 31, 2014, except for the warrants issued to Genextra S.p.A., all of the warrants have either been exercised or expired in accordance with their terms. Certain of the warrants that were outstanding during the first quarter of 2013 and 2014 included a provision that provides for a reduction in the warrant exercise price upon subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision, including the warrants held by Genextra S.p.A., are deemed to be derivative instruments and as such, are recorded as a liability and marked-to-market at each reporting period. Certain other warrants outstanding during the first quarter of 2013 included a provision that required the shares underlying the warrants to be registered upon the completion of an initial public offering. As a result, these warrants were reclassified as a liability as of the date of our initial public offering and were also marked-to-market at each reporting date since the offering. The fair value estimates of these warrants are determined using a Black-Scholes option-pricing model and are based, in part, on subjective assumptions and could differ materially in the future. Non-cash changes in the fair value of the common stock warrant liability from the prior period is recorded as a component of other income and expense.

## Results of Operations

### *Comparison of the Three Months Ended March 31, 2013 and the Three Months Ended March 31, 2014*

The following table summarizes our results of operations for each of the three months ended March 31, 2013 and 2014, together with the changes in those items in dollars:

|                             | Three Months Ended |             | Dollar<br>Change |
|-----------------------------|--------------------|-------------|------------------|
|                             | March 31,<br>2013  | 2014        |                  |
|                             | (In thousands)     |             |                  |
| Licensing revenue           | \$405              | \$405       | \$-              |
| Operating expenses:         |                    |             |                  |
| Research and development    | 4,832              | 25,930      | 21,098           |
| General and administrative  | 2,397              | 5,651       | 3,254            |
| Loss from operations        | (6,824 )           | (31,176 )   | (24,352 )        |
| Warrant revaluation expense | (3,683 )           | (226,627)   | (222,944)        |
| Other income, net           | 296                | 136         | (160 )           |
| Net loss                    | \$(10,211)         | \$(257,667) | \$(247,456)      |

#### *Licensing Revenue*

Licensing revenue was \$405,000 and \$405,000 for the three months ended March 31, 2013 and 2014, respectively, resulting from the amortization of the up-front payments from the collaboration agreements entered into with DSP.

#### *Research and Development Expenses*

Research and development expenses were \$4.8 million and \$25.9 million for the three months ended March 31, 2013 and 2014, respectively, representing an increase of \$21.1 million. This increase in research and development expense primarily reflects:

- increased non-cash stock-based compensation expense of approximately \$16.9 million, primarily related to the remeasurement of previously granted options to consultants;



- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation, bonus, and benefits expense of approximately \$1.0 million;
- increased Phase 1 clinical trial costs in support of the NDA/MAA filings of approximately \$1.8 million;
- increased indirect costs of approximately \$561,000 primarily due to increased legal costs related to our patent portfolio of \$219,000, increased rent and utilities of approximately \$100,000 and increased travel related costs of \$100,000; and
- increased consulting costs in support of our anticipated NDA/MAA filings of approximately \$312,000.

#### *General and Administrative Expenses*

General and administrative expenses were \$2.4 million and \$5.6 million in the three months ended March 31, 2013 and 2014, respectively. The \$3.2 million increase primarily reflects:

- increased pre-commercial activities, including an increase in personnel resulting in increased compensation and related benefits, of approximately \$1.5 million;
- an increase in non-cash stock-based compensation expense of approximately \$500,000;
  - an increase in personnel to manage the increased activities due to our operating as a public company, resulting in increased compensation and the related benefit expense of approximately \$482,000;
- increased legal expenses of approximately \$200,000;
- increased accounting and filing fees of approximately \$200,000; and
- increased rent and utilities of approximately \$175,000.

### *Revaluation of Warrants*

Our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair values of the warrants were determined by us using a Black-Scholes option-pricing model, resulting in the recognition of a loss of \$3.7 million and \$226.6 million for the three months ended March 31, 2013 and 2014, respectively. These fluctuations in value were primarily due to the increase in the price of our common stock underlying the warrants, slightly offset by the declines in the estimated life of the warrants and changes in volatility of the shares of common stock underlying the warrants.

### *Other Income, Net*

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which decreased compared to the prior year period as a result of the increase in the amortization of investment premiums.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

We have incurred losses of \$443.6 million and utilized net cash of \$107.9 million to fund operations since our inception in September 2002 through March 31, 2014. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Since our inception through March 31, 2014, we have funded our operations primarily through the sale of common stock, preferred stock, convertible notes and warrants, totaling \$250.4 million (net of issuance costs) including \$29.7 million in net proceeds from our Series C financing in August 2012, \$78.7 million in net proceeds from our initial public offering in October 2012, and \$61.2 million in net proceeds from our follow-on public offering in June 2013, and the receipt of \$16.4 million in up-front payments under our licensing and collaboration agreements with DSP and Servier. As of March 31, 2014, we had cash, cash equivalents and investment securities of approximately \$134.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily

with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts and investments, all of which have maturities of less than two years.

In April 2014, we completed a follow-on public offering of 1,000,000 shares of our common stock, of which 600,000 shares were sold by us and 400,000 shares were sold by certain selling stockholders, at a public offering price of \$320.00 per share. After underwriting discounts and commissions and estimated offering expenses, we received net proceeds from the offering of approximately \$183.4 million. We did not receive any proceeds from the sale of shares of common stock by the selling stockholders.

### *Cash Flows*

The following table sets forth the significant sources and uses of cash for the periods set forth below:

|   | Three Months<br>Ended March 31, |            |
|---|---------------------------------|------------|
|   | 2013                            | 2014       |
|   | (In thousands)                  |            |
| Net cash provided by (used in):           |                                 |            |
| Operating activities                      | \$(5,636 )                      | \$(12,318) |
| Investing activities                      | (8,252 )                        | 7,706      |
| Financing activities                      | 87                              | 2,460      |
| Net decrease in cash and cash equivalents | \$(13,801)                      | \$(2,152 ) |

*Operating Activities.* Net cash used in operating activities of \$5.6 million during the three months ended March 31, 2013 was primarily a result of our \$10.2 million net loss, offset by the add-back of non-cash expenses of \$1.6 million for stock-based compensation and \$3.7 million for warrant liability revaluation. Net cash used in operating activities of \$12.3 million during the three months ended March 31, 2014 was primarily a result of our \$257.7 million net loss, offset by the add-back of non-cash expenses of \$19.1 million for stock-based compensation and \$226.6 million for warrant liability revaluation, the amortization of investment premium of \$552,000 and net changes in operating assets and liabilities of \$1.0 million.

*Investing Activities.* Net cash provided by investing activities for the three months ended March 31, 2014 was \$7.7 million as compared to net cash of \$8.3 million used in investing activities during the same period in 2013. This increase of approximately \$15.9 million is attributed to the increase in the sale of our investments of \$21.7 million offset by increased purchases of investments of \$5.5 million.

*Financing Activities.* Net cash provided by financing activities for the three months ended March 2014 were \$2.5 million compared to \$87,000 for the comparable period in 2013. This increase was primarily the result of funds received through the exercise of stock options.

### **Future Funding Requirements**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize OCA or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We have incurred and expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our currently expected level of operating expenditures, we believe that our existing cash, cash equivalents, short-term investments, including the \$183.4 million of net proceeds we received from the sale of our common stock in April 2014, and anticipated funding under our DSP and Servier collaborations, will enable us to fund our operating expenses and capital expenditure requirements through 2016. Although our current plans are still preliminary and subject to change, our current estimate reflects, among other items, the planned initiation of our confirmatory clinical outcomes trial of OCA in PBC and engaging in other planned activities for seeking regulatory approval of OCA in PBC, including several Phase 1 pharmacology clinical trials; the planned initiation of a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients; the anticipated initiation of a Phase 2 clinical trial of OCA in PSC; an anticipated increase in pre-commercial and commercial activities for OCA, including activities in preparation of the potential commercial launch of OCA in PBC; the planned initiation of our Phase 3 program in NASH; and pre-clinical studies anticipated to be needed for the submission of an IND for INT-767 and the planned initiation of a Phase 1 clinical trial for INT-767. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

The amount and timing of our future funding requirements will depend on many factors, including:

• the results of, and the data from, the Phase 2b FLINT trial of OCA in NASH patients and our other clinical trials;

• the willingness of the FDA and EMA to accept our POISE trial, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC;

• the progress, costs, results of and timing of our planned confirmatory clinical outcomes trial of OCA for the treatment of PBC;

• the progress, costs, results of and timing of clinical development of OCA for other indications, including any additional clinical trials that may be needed to continue our development of, and to seek regulatory approval for, OCA in NASH;

• the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;

• the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-767, and whether we pursue their development independently or with a third-party collaborator;

• the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;

• our need to expand our research and development activities;

• the costs associated with securing and establishing commercialization and manufacturing capabilities and procuring the materials necessary for the manufacturing of our product candidates;

- market acceptance of our product candidates;

- the costs of acquiring licensing or investing in business, products, product candidates and technologies;

our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or to the intellectual property rights;

our need and ability to hire additional management, scientific and medical, commercial and other qualified personnel;

the effect of competing technological and market developments;

our need to implement additional internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts; and

the economic and other terms, timing of and success of our existing licensing arrangement and any collaboration, licensing or other arrangement into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

### **Contractual Obligations and Commitments**

Other than as described below, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014.

On May 1, 2014, we entered into a lease agreement with The Irvine Company LLC for our new office in San Diego. The lease will provide us with approximately 47,000 rentable square feet in San Diego for office space. The lease term is anticipated to commence in September 2014 and is anticipated to end in September 2019. We also have an option to further extend the lease for an additional five year term at market rates prevailing at such time.

The rent for the first year will be approximately \$874,000 without giving effect to rent abatements and the rent will gradually increase every 12 months during the lease term. During the first six months, we will receive a partial rent abatement from the landlord. The landlord will also provide us with contributions of up to approximately \$2.4 million for improvements to the office space.

Pursuant to the terms of the new lease, we have provided the landlord with a letter of credit for \$874,000, which will decrease at certain times during the term of the lease.

The Irvine Company LLC, which is also the landlord of our current San Diego office, has agreed to release us from our obligations under the current San Diego lease effective as of the commencement date of the lease for our new San Diego office.

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

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under rules of the Securities and Exchange Commission.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates and there have been no material changes since our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014.

#### **Item 4. Controls and Procedures**

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

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of March 31, 2014, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## **PART II OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

On February 21, 2014 and February 28, 2014, purported shareholder class actions, styled *Scot H. Atwood v. Intercept Pharmaceuticals, Inc. et al.* and *George Burton v. Intercept Pharmaceuticals, Inc. et al.*, respectively, were filed in the United States District Court for the Southern District of New York, naming us and certain of our officers as defendants. These lawsuits were filed by stockholders who claim to be suing on behalf of anyone who purchased or otherwise acquired our securities between January 9, 2014 and January 10, 2014.

The lawsuits allege that we made material misrepresentations and/or omissions of material fact in our public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to our January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that our January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. The plaintiffs in each suit seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees. On April 22, 2014, two individuals each moved to consolidate the cases and to be appointed as the lead plaintiff. Those motions are currently pending before the Court.

Additional complaints may be filed against us and our directors and officers related to our disclosures.

We believe that these lawsuits are without merit. At this time, no assessment can be made as to the likely outcome of these lawsuits or whether the outcome will be material to us. Therefore, we have not accrued for any loss contingencies related to these lawsuits.

### **Item 1A. Risk Factors.**

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2013 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in such filings.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

### **Recent Sales of Unregistered Securities**

Set forth below is information regarding securities sold by us during the three months ended March 31, 2014 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and March 31, 2014, we did not issue or sell any shares on an unregistered basis. On April 10, 2014, we issued an aggregate of 834,758 shares of common stock upon the cashless exercise by Genextra S.p.A. of all of its warrants to purchase a total of 865,381 shares of common stock. No underwriters were involved in the foregoing sales of securities. The securities described above were issued and sold in reliance on the exemptions from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act. Genextra S.p.A. represented to us in connection with its purchase that it was acquiring the securities for investment and not for distribution and that it could bear the risks of the investment. Genextra S.p.A. received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from registration.

### **Purchase of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

### **Use of Proceeds from Registered Securities**

On October 10, 2012, we completed our initial public offering of 5,750,000 shares of our common stock at a price of \$15.00 per share for aggregate gross proceeds of approximately \$86.3 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on October 10, 2012 (File No. 333-183706), and a registration statement on Form S-1 filed pursuant to Rule 462(b) of the Securities Act (File No. 333-184370).

We received aggregate net proceeds from the offering of approximately \$78.7 million, after deducting approximately \$6.1 million of underwriting discounts and commissions, and approximately \$1.5 million of estimated offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

We invested the net proceeds from the offering in a variety of capital preservation investments, including money market funds, U.S. Treasury notes and high quality marketable debt instruments of corporate, financial institutions, and government sponsored enterprises. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

As of March 31, 2014, we have not used any of the net proceeds from the initial public offering.

### **Item 3. Defaults Upon Senior Securities.**

None.

### **Item 4. Mine Safety Disclosures.**

None.

### **Item 5. Other Information.**

None.

28

**Item 6. Exhibits.**

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

**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.

**INTERCEPT PHARMACEUTICALS, INC.**

Date: May 9, 2014 By: /s/ Mark Pruzanski, M.D.  
Mark Pruzanski  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 9, 2014 By: /s/ Barbara Duncan  
Barbara Duncan  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Exhibit Index**

| <b>Exhibit<br/>Number</b> | <b>Description of Exhibit</b>  |
|---------------------------|--|
| 10.1                      | Non-Employee Director Compensation Policy.#  |
| 10.2                      | Employment Agreement by and between the Registrant and Rachel McMinn, effective as of April 30, 2014.#   |
| 10.3                      | Form of Restricted Stock Award Grant Notice for Directors under the 2012 Equity Incentive Plan of the Registrant.#   |
| 10.4                      | Form of Restricted Stock Award Grant Notice for Employees and Consultants under the 2012 Equity Incentive Plan of the Registrant.#   |
| 31.1                      | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2                      | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1                      | Certification of Principal Executive Officer and 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                       | The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2013 and March 31, 2014 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month periods ended March 31, 2013 and 2014 (unaudited), and the period from September 4, 2002 (inception) through March 31, 2014 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2013 and 2014 (unaudited) and for the period from September 4, 2002 (inception) to March 31, 2014 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited).+ |

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# Management or director compensation plan or policy.

Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.