INTERCEPT PHARMACEUTICALS INC
Form 10-Q
May 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**22-3868459**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
18 Desbrosses Street New York, NY (Address of Principal Executive Offices)	**10013 (Zip Code)**

(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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated 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 ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of May 1, 2013, there were 16,805,191 shares of common stock, $0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

(A Development Stage Company)

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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,” “w
“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 future 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 ability to obtain additional financing;
- our use of the proceeds from our recently completed initial public offering;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; 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 April 1, 2013, particularly in Item 1.A. Risk Factors, that 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, 2012 (Audited)	March 31, 2013 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$45,511,641	$31,711,264
Investment securities, available-for-sale	64,682,270	72,508,832
Prepaid expenses and other current assets	1,584,308	1,572,450
Total current assets	111,778,219	105,792,546
Fixed assets, net	148,838	134,852
Security deposits	251,540	268,707
Total assets	$112,178,597	$106,196,105
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$3,745,773	$3,225,749
Short-term portion of warrant liability	7,596,659	4,786,036
Short-term portion of deferred revenue	1,621,622	1,621,622
Total current liabilities	12,964,054	9,633,407
Long-term liabilities:		
Long-term portion of warrant liability	22,762,135	25,627,190
Long-term portion of deferred revenue	10,540,543	10,135,138
Total liabilities	46,266,732	45,395,735
Stockholders' equity:		
Common stock. 25,000,000 shares authorized; 16,526,885, and 16,633,964 shares issued and outstanding as of December 31, 2012 and March 31, 2013, respectively; par value $0.001 per share	16,527	16,633
Additional paid-in capital	184,100,139	189,422,716
Accumulated other comprehensive loss, net	(21,451)	(245,481)
Accumulated deficit during development stage	(118,183,350)	(128,393,498)
Total stockholders' equity	65,911,865	60,800,370
Total liabilities and stockholders' equity	$112,178,597	$106,196,105

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 March 31,		Period From September 4, 2002 (Inception) Through March 31, 2013
	2012	2013	
Licensing revenue	$758,754	$405,405	$ 4,656,640
Costs and expenses:			
Research and development	3,059,585	4,832,556	76,267,247
General and administrative	1,059,202	2,396,854	31,994,936
Total costs and expenses	4,118,787	7,229,410	108,262,183
Other income (expense):			
Revaluation of warrants	677,907	(3,682,505)	(26,758,081)
Foreign currency loss on liquidation	—	—	(191,733)
Other income, net	2,434	296,362	1,672,900
QTDP Grant	—	—	488,959
	680,341	(3,386,143)	(24,787,955)
Net loss	(2,679,692)	(10,210,148)	(128,393,498)
Dividends on preferred stock, not declared	(750,000)	—	(10,944,134)
Net loss attributable to common stockholders	$(3,429,692)	$(10,210,148)	$ (139,337,632)
Net loss per share, basic and diluted	$(1.03)	$(0.62)	
Weighted average shares outstanding, basic and diluted	3,329,666	16,558,297	
Other comprehensive gain/(loss):			
Unrealized (loss) on investment securities	—	(245,481)	(266,932)
Foreign currency translation adjustments	12,577	—	—
Total comprehensive loss	$(2,667,115)	$(10,455,629)	$ (128,660,430)

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 September 4, 2002 (Inception) Through March 31, 2013
	2012	2013	
Cash flows from operating activities:			
Net loss	$ (2,679,692)	$ (10,210,148)	$ (128,393,498)
Adjustments to reconcile net loss to net cash used in operating activities:			
Revaluation of warrants	(677,907)	3,682,505	26,758,081
Stock-based compensation	391,856	1,607,181	11,385,051
Impairment of bonds	—	—	151,402
Loss from sale of assets	—	—	217,296
Depreciation	74,353	22,650	2,389,318
Foreign currency loss on liquidation	—	—	191,733
Amortization of investment premium	—	—	118,180
Changes in:			
Prepaid expenses and other current assets	(231,781)	187,568	(1,172,052)
Accounts payable, accrued expenses, and other current liabilities	(11,308)	(520,024)	3,225,754
Deferred revenue	(758,754)	(405,405)	11,756,760
Interest accrued on promissory notes	—	—	91,249
Net cash used in operating activities	(3,893,233)	(5,635,673)	(73,280,726)
Cash flows from investing activities:			
Investments in certificates of deposit	(4,001)	—	(627,631)
Purchases of investment securities	—	(10,243,468)	(76,184,444)
Sales of investment securities	—	2,000,000	3,119,075
Purchases of equipment, improvements, and furniture and fixtures	(19,814)	(8,664)	(1,405,902)
Net cash used in investing activities	(23,815)	(8,252,132)	(75,098,902)
Cash flows from financing activities:			
Proceeds from issuance of stock offerings, net of issuance costs	—	—	172,477,162
Proceeds from issuance of common stock warrants	—	—	7,385,897
Payments of capital lease obligation	(58,525)	—	(1,335,567)
Proceeds from exercise of options	—	87,428	130,133
Proceeds from exercise of warrants	—	—	375,000
Proceeds from issuance of convertible promissory notes payable	—	—	1,250,000
Net cash provided by (used in) financing activities	(58,525)	87,428	180,282,625

Effect of exchange rate changes	12,577	—	(191,733)
Net increase (decrease) in cash and cash equivalents	(3,962,996)	(13,800,377)	31,711,264
Cash and cash equivalents – beginning of period	17,707,476	45,511,641	—
Cash and cash equivalents – end of period	$ 13,744,480	$ 31,711,264	$ 31,711,264
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 7,474	$ —	$ 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	4,646,292

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

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 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. Prior to April 2011, the Company operated a wholly-owned subsidiary in Italy where its bile acid receptor research was primarily conducted. In April 2011, the Company began the process of liquidating this subsidiary and has since disposed of all assets. However, the Company is continuing its early stage TGR5 research through its collaboration with Les Laboratories Servier and Institut de Recherches Servier, or collectively Servier. Effective March 15, 2013, the Company decided to remove the Italian subsidiary from the legal liquidation process to act 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.

On September 13, 2012, the board of directors of the Company approved, and on September 25, 2012 the stockholders of the Company approved, a one-for-5.7778 reverse stock split of the Company's outstanding common stock, which was effected on September 26, 2012. Stockholders entitled to fractional shares as a result of the reverse stock split received a cash payment in lieu of receiving fractional shares. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's series A preferred stock, series B preferred stock, and series C preferred stock were proportionately reduced and the respective conversion prices were proportionately increased. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

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 April 1, 2013. The results for the three months ended March 31 , 2012 and March 31, 2013 (unaudited), and for the period from inception (September 4, 2002) through March 31, 2013 (unaudited) are not necessarily indicative of results to be expected for the year ending December 31, 2013, 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). 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 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.

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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, 2012 and 2013, the Company recorded revenue of $405,000 (unaudited) and $405,000 (unaudited), 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, 2013 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.

Les Laboratories Servier and Institut de Recherches Servier

In August 2011, the Company entered into a research collaboration agreement with Servier under which the Company granted Servier the exclusive license to research, develop and commercialize TGR5 agonists (other than the Company's preclinical product candidates INT-767 and INT-777) for use in the treatment of diabetes, obesity, atherosclerosis and reperfusion injury in all countries other than the United States and Japan. The agreement expires when no payment obligations are or will become due and may be terminated earlier by the parties in certain circumstances.

Under the terms of the agreement, the Company received an up-front payment from Servier of $1.4 million. The Company is also eligible to receive up to an aggregate of approximately €8.5 million in development milestones based on the initiation of clinical trials by Servier or the selection by Servier of product candidates for development, including a payment of €4.0 million upon the determination by Servier to initiate a Phase 3 clinical trial for the first product candidate under the agreement. The Company may also receive up to an aggregate of approximately €10.0 million in regulatory submission and approval milestones, including a payment of €5.0 million upon the first product candidate under the agreement achieving regulatory approval in the EU for its initial indication. The agreement also contemplates up to an aggregate of approximately €90.0 million in sales milestones, including a payment of €10.0 million upon the first product candidate under the agreement achieving its first commercial sale, €10.0 million upon achieving net sales of €200.0 million for a product, €20.0 million upon achieving net sales of €400.0 million for a product, €25.0 million for achieving net sales of €500.0 million for a product and €25.0 million for achieving net sales of €600.0

million for a product. Servier is also obligated to pay the Company royalties based on net sales of products developed under the agreement on a country-by-country basis. Servier is also obligated to pay the Company royalties based on net sales of products developed under the agreement on a country-by-country basis.

Intercept and Servier will jointly support the discovery effort, while Servier alone will be responsible for all costs associated with the global development, regulatory approval and commercialization of any compound selected as a lead candidate by the parties. The Company agreed to reimburse Servier up to a mid-double digit percentage of the total historical development costs incurred by Servier in relation to clinical development activities aimed at achieving regulatory approval in the European Union and the United States if the Company enters into a partnership agreement, or commences development or commercialization activities, with respect to any such compound in the United States. Servier may credit a portion of any reimbursable development costs against any milestone or royalty payments due and payable to the Company by Servier under the research collaboration agreement until all such reimbursable amounts are repaid. During the three months ended March 31, 2012 and 2013, the Company did not reimburse any development costs to Servier nor is it expected that any such costs will be reimbursed during 2013, as no such reimbursable developments costs are planned during the period.

The Company evaluated the research collaboration agreement with Servier and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company’s substantive performance obligations under this research collaboration include an exclusive license to its technology, technical, scientific and intellectual property support to the research plan during the first year of the agreement and participation on an executive committee and a research and development committee. The Company determined that these performance obligations represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company’s technical expertise and committee participation during the initial 12-month period. The research portion of the collaboration may be extended by mutual agreement by the parties for one or more additional years. In July 2012, the term of the research program was extended until January 31, 2013, on the same financial terms as the existing research program, including the reimbursement by Servier of the full time equivalent costs incurred by the Company in the conduct of the research program, up to a set maximum amount. In February 2013, the research program was further extended until July 31, 2013 on the same financial terms as the existing agreement. The up-front payment was recognized ratably over the estimated 12-month performance period as the research and development and executive committee services were provided. During the three months ended March 31, 2012, the Company recorded revenue of $354,000 related to the Company’s efforts under the Servier arrangement, which was recorded in “Licensing Revenue” in the Company’s Consolidated Statement of Operations. As the up-front payment was fully recognized as of September 30, 2012, no revenue was recorded during the three month period ended March 31, 2013 and no further revenue will be recognized for the up-front payment. The Company determined that each potential future development, regulatory and sales milestone is substantive.

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The Company receives reimbursement from Servier for research services outlined in the agreements in which the Company engaged Professor Pellicciari and TES Pharma SRL (TES) as described below. The Company recognizes this expense reimbursement as a reduction of research and development expenses as the Company is acting as an agent regarding these research activities. All amounts incurred by the Company for research under the Servier agreement during the three months ended March 31, 2013, including the amounts incurred under the related agreements with Professor Pellicciari and TES, were covered under the Servier agreement. At December 31, 2012 and March 31, 2013, the Company recorded $496,000 and $481,000, respectively in prepaid expenses and other assets for amounts due from Servier for such expense reimbursement.

Sponsored Research Agreement (SRA) with the University of Perugia and Professor Pellicciari

The Company is engaged in a sponsored research agreement with the University of Perugia and Professor Roberto Pellicciari, a founder of the Company, to design, synthesize, optimize, scale-up, and develop pharmacologically active ligands for bile acid receptors. Under the SRA, the Company is assigned ownership of any patent and intellectual property rights arising from the research project. The Company paid the University of Perugia €100,000 quarterly commencing July 1, 2006 through 2010 and €100,000 for the fiscal year 2011. In 2012, the Company amended and restated the SRA to extend the term to the end of 2012 and paid the University of Perugia €80,000 during fiscal 2012. The Company recognized expense for the three months ended March 31, 2012 and 2013 of $33,000 and $26,000, respectively. In April 2013, by mutual agreement of the parties, the term of this agreement was extended, effective as of January 1, 2013, until December 31, 2013 on the same financial terms as were previously in effect.

Consulting Agreements with Professor Pellicciari

The Company entered into an amended and restated consulting and intellectual property agreement with Professor Pellicciari on November 1, 2008, which was amended on October 27, 2010. Pursuant to this agreement, as amended, the Company was required to pay Professor Pellicciari €8,000 per month through December 31, 2010 for consulting services. The agreement also required the Company to make a lump sum payment of €172,500 and monthly payments of €12,000 through December 31, 2010 for the assignment of certain intellectual property rights. The Company entered into amended and restated consulting and intellectual property agreements with Professor Pellicciari on January 1, 2011 and January 1, 2012, pursuant to which the Company agreed to pay Professor Pellicciari an aggregate of €100,000 per year for services provided through December 31, 2012 for consulting services and intellectual property rights in

relation to OCA, INT-767 and INT-777 product candidates. In April 2013, by mutual agreement of the parties, the term of this agreement was extended, effective as of January 1, 2013, until December 31, 2013 on the same financial terms as were previously in effect.

On August 1, 2011, the Company signed a separate agreement with Professor Pellicciari for consulting services and intellectual property rights related to his services on the TGR5 program and the Servier license, pursuant to which the Company agreed to pay him an aggregate of €150,000 for his services through July 31, 2012. This agreement also provided that Professor Pellicciari will be eligible for a performance bonus of €50,000 based on the results of the research collaboration. The performance bonus is a discretionary bonus based upon the Company's assessment of the success of the initial work performed under the collaboration, as extended. No such bonus was agreed upon by the parties as of December 31, 2012. In July 2012 and February 2013, by mutual agreement of the parties, the term of this agreement was extended until January 31, 2013 and July 31, 2013, respectively, in conjunction with the extension of the term of the research program with Servier, on the same financial terms as the original consulting agreement with Professor Pellicciari.

The Company recognized expense related to these agreements for the three months ended March 31, 2012 and 2013 of $85,000, and $82,000, respectively.

TES Pharma SRL (TES)

In August 2011, the Company contracted with TES to provide research and development services for the Company's TGR5 program through July 31, 2012 to enable the Company to uphold its obligations for providing such services under the Servier agreement described above. Professor Pellicciari is an owner of TES. The Company is required under the agreement to pay TES an aggregate amount of €250,000 each quarter during the term of the agreement. The agreement provides that any funds paid to TES that have not been expended or irrevocably committed at the expiration of the agreement will be refunded to the Company.

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The agreement has a term of one year unless the Company, in its sole discretion, extends the term of this agreement for one additional year on the same terms and conditions as the current agreement. In July 2012 and February 2013, by mutual agreement of the parties, the term of this agreement was extended until January 31, 2013 and July 31, 2013, respectively, in conjunction with the extension of the term of the research program with Servier, on the same financial terms as the original agreement with TES.

The Company incurred charges related to this agreement for the three months ended March 31, 2012 and 2013 of $337,000 and $333,000, respectively.

National Institute of Diabetes and Digestive and Kidney Disease Institute (NIDDK)

In 2010, the Company contracted with the NIDDK of the National Institute of Health to research the effects of OCA for the treatment of patients with NASH in a Phase 2b clinical trial called the FLINT trial. Under the contract with the NIDDK, the Company made a milestone payment of $1.0 million in June 2012 following notification in June 2012 that the FLINT trial will continue based upon the results of a blinded interim analysis and a payment of $1.25 million following the completion of enrollment in the trial in November 2012. The Company does not have any additional contractual payments remaining.

WIL Research Laboratories, LLC (WIL)

On October 2, 2007, the Company entered into a master laboratory services agreement with WIL Research Laboratories, LLC to perform certain research and laboratory services. The agreement was amended in October 2011. The agreement has a term ending on October 2, 2013, and automatically extends for successive one year periods, unless either party gives written notice to the other party at least 60 days prior to the end of the current term. Either the Company or WIL may terminate the agreement upon 90 days written notice. However, if a work order pertaining to the ongoing studies is outstanding, WIL may not terminate the agreement with 90 days written notice until the work order has been completed or otherwise terminated.

On November 16, 2011, the Company finalized two work orders with WIL for FDA-required studies in mice and rats to investigate the presence or absence of carcinogenic potential of OCA. The Company agreed to pay an aggregate of $4.0 million for the studies, consisting of a combination of quarterly installment payments of approximately $300,000 and milestone payments totaling approximately $400,000 upon delivery of final result reports. If additional costs are incurred beyond the amounts specified in the work orders, the Company agreed to pay such reasonable additional costs upon receipt of proper invoice. The Company anticipates that all the studies will continue through completion, all milestones will be satisfied and that it will pay to WIL $4.0 million under this agreement. The Company recognized expense related to these contracts and other work orders for the three months ended March 31, 2012 and 2013 of $446,500 and $315,000, respectively.

3. Investments

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2012 and March 31, 2013:

	As of December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$45,512	$ —	$ —	$45,512
Investment Securities:				
Commercial paper	12,971	10	(15)	12,966
Corporate debt securities	41,866	7	(23)	41,850
U.S. government and agency securities	9,861	4	—	9,865
Total investments	64,698	21	(38)	64,681
Total cash, cash equivalents and investments	$110,210	$ 21	$ (38)	$110,193

INTERCEPT PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

	As of March 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$31,711	$ —	$ —	$31,711
Investment Securities:				
Commercial paper	14,980	1	(6)	14,975
Corporate debt securities	45,651	10	(15)	45,646
U.S. government and agency securities	11,804	6	—	11,810
Certificate of deposit	78	—	—	78
Total investments	72,513	17	(21)	72,509
Total cash, cash equivalents and investments	$104,224	17	(21)	104,220

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, 2012	
	Less than 12 months	
	Fair Value	Gross Unrealized Holding Losses
	(In thousands)	
Commercial paper	$ 10,461	$ (15)
Corporate debt securities	29,834	(23)
Total available-for-sale securities	$ 40,295	$ (38)

	As of March 31, 2013	
	Less than 12 months	
	Fair Value	Gross Unrealized Holding Losses

	(In thousands)			
Commercial paper	$ 11,978	$	(6	)
Corporate debt securities	31,285		(15	)
Total available-for-sale securities	$ 43,263	$	(21	)

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4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2012	March 31, 2013
	(In thousands)	
Prepaid expenses	$970	$ 1,063
Contract receivable	496	481
Certificates of deposit	77	—
Refundable tax credits	42	28
Prepaid expenses and other current assets	$1,585	$ 1,572

5. Fixed Assets, Net

Fixed assets, net consisted of the following:

	December 31, 2012	March 31, 2013
	(In thousands)	
Office equipment	$357	$ 362
Leasehold improvements	178	178
Furniture and fixtures under capitalized lease	157	157
Furniture and fixtures	121	125
Subtotal fixed assets	813	822
Less: accumulated depreciation and amortization	(664)	(687)
Fixed assets, net	$149	$ 135

Depreciation and amortization expense for the three months ended March 31, 2012 and 2013 was $74,000 and $23,000, respectively.

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6. Accounts Payable, Accrued Expenses and Other Liabilities

Accounts payable, accrued expenses and other liabilities consisted of the following:

	December 31, 2012	March 31, 2013
	(In thousands)	
Accounts payable	$1,180	$ 1,341
Accrued employee compensation	1,335	516
Accrued contracted services and other	1,231	1,369
Accounts payable, accrued expenses and other liabilities	$3,746	$ 3,226

7. 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, 2012 and March 31, 2013, the

Company had available net operating loss carryforwards to reduce future taxable income of approximately $70.2 million and $75.5 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 $42.1 million and $45.1 million at December 31, 2012 and March 31, 2013, 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.

8. 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 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.

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The Company will continue to adjust the fair value of the common stock warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable common stock warrants or until such time that the warrants are no longer determined to be derivative instruments.

As of March 31, 2013, the Company had outstanding warrants to purchase a total of 1,042,985 shares of its common stock, at a weighted average exercise price of $9.76 per share. Of these warrants, 55,339 expire in May 2013; 102,656 expire in October 2013; 19,609 expire in May 2014; and 865,381 expire in January 2015, in each case if not exercised. All of these warrants are “in the money” based on the market price of our common stock as of March 31, 2013.

9. 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).

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 Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
December 31, 2012				
Assets:				
Money market funds	$24,862	$24,862	$ —	$ —
Available for sale securities:				
Commercial paper	$12,966	$—	$ 12,966	$ —
Corporate debt securities	41,850	—	41,850	—
U.S. government and agency securities	9,865	—	9,865	—
Total assets:	$89,543	$24,862	$ 64,681	$ —
Liabilities:				
Warrants to purchase common stock	$(30,359)	$—	$ —	$ (30,359)
Total liabilities	$(30,359)	$—	$ —	$ (30,359)
March 31, 2013				
Assets:				
Money market funds	$17,352	$17,352	$ —	$ —
Available for sale securities:				
Commercial paper	$14,975	$—	$ 14,975	$ —
Corporate debt securities	45,646	—	45,646	—
U.S. government and agency securities	11,809	—	11,809	—
Certificate of deposit	78	—	78	—
Total assets:	$89,860	$17,352	$ 72,508	$ —
Liabilities:				
Warrants to purchase common stock	$(30,413)	$—	$ —	(30,413)
Total liabilities	$(30,413)	$—	$ —	$ (30,413)

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The estimated fair value of marketable debt securities (commercial paper, corporate debt securities, U.S. government and agency securities and certificates of deposit) as of March 31, 2013, by contractual maturity, are as follows:

	Fair Value (In thousands)
Due in one year or less	$ 47,180
Due after one year through 2 years	25,329
Total investments in debt securities	$ 72,509

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

10. 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.

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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.

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 were converted into 7,403,817 shares of common stock and all accrued dividends on the preferred stock were eliminated.

11. 2003 Stock Incentive Plan and 2012 Stock Plan

In 2003, the Board of Directors and the stockholders of the Company approved the Amended and Restated 2003 Stock Incentive Plan (2003 Plan) which provided for the granting of restricted stock, stock options and other stock-related awards to officers, directors, employees, advisors, and consultants of the Company. Stock options were granted at exercise prices not less than the fair market value of the Company’s common stock at the dates of grant. In May 2006, June 2008 and January 2010, the number of common shares available was increased to 519,228, 865,381, and 1,384,610, respectively. Most options are scheduled to vest over a period of up to four years. The 2003 Plan was terminated upon the pricing of the IPO in October 2012, and 555,843 shares available under the 2003 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.

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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. On January 1, 2013, the numbers of shares reserved for issuance under the 2012 Plan was increased by 661,075 shares as a result of the automatic increase in shares reserved pursuant to the terms thereof. As of March 31, 2013, there were 878,174 shares of common stock authorized for issuance under the 2012 Plan (including the 555,843 shares of common stock that were added from the 2003 Plan, plus such additional shares as are forfeited or canceled under the 2003 Plan).

The following table summarizes stock option activity during the three months ended March 31, 2013:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2012	1,526,150	$ 10.67
Granted	130,000	37.69
Exercised	(8,652)	10.11
Forfeited	(1,589)	8.67
Outstanding, March 31, 2013	1,645,909	$ 12.81
Exercisable, March 31, 2013	1,184,273	$ 9.64

On November 16, 2012, the Company granted to employees and directors restricted stock units ("RSUs") for 173,592 shares of common stock under the 2012 Plan. As of March 31, 2013 none of the RSUs were vested.

12. Net Loss Per Share

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

	Three Months Ended March 31,	
	2012	2013
	(In thousands, except share and per share amounts)	
Historical net loss per share		
Numerator:		
Net loss attributable to common stockholders	$ (3,430)	$ (10,210)
Denominator:		
Weighted average shares outstanding, basic and diluted	3,329,666	16,558,297
Net loss per share, basic and diluted	$ (1.03)	$ (0.62)

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

	As of March 31,	
	2012	2013
	(In thousands)	
Shares issuable upon conversion of preferred stock	4,808	—
Shares issuable pursuant to accumulated preferred stock dividend	1,045	—
Options	1,309	1,646
Warrants to purchase common stock	1,233	1,043
Restricted stock units	—	176
Total	8,395	2,865

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, 2012 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2013. 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 this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, 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 diseases 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.

We have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through March 31, 2013, we have funded our operations primarily through the private and public sales of preferred stock, common stock, convertible notes and warrants to purchase common stock totaling $181.5 million (net of issuance costs of $9.9 million), including $29.7 in net proceeds from our Series C financing in August 2012 and $78.7 million in net proceeds from our initial public offering, or IPO, in October 2012, and through the receipt of $16.4 million of up-front payments under our collaborative agreements.

On October 16, 2012, we completed the IPO pursuant to a registration statement on Form S-1. In the IPO, we 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 offering expenses payable by us. Upon the closing of the IPO, all outstanding shares of our preferred stock were converted into 7,403,817 shares of common stock.

We have incurred net losses in each year since our inception in 2002. Our net losses were approximately $2.7 million and $10.2 million for the three months ended March 31, 2012 and 2013, respectively. As of March 31, 2013, we had

an accumulated deficit of approximately $128.4 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, obeticholic acid, or OCA, for the treatment of primary biliary cirrhosis, or PBC;
- seek to obtain regulatory approvals for OCA;
- 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 our research and development efforts with our preclinical development compounds, such as INT-767 and INT-777;
- 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.

Prior to April 2011, we operated a wholly-owned subsidiary in Italy where our bile acid receptor research was primarily conducted. Subsequently, until March 15, 2013, our Italian subsidiary was in the process of voluntary liquidation under Italian law. Effective March 15, 2013, we have decided to remove our Italian subsidiary from the liquidation process and it will continue to act as our legal representative for our clinical trials in the European Union to satisfy European Union regulatory requirements. Although our Italian subsidiary was undergoing the liquidation process from April 2011 through March 2013, we have continued our early stage TGR5 research program through our collaboration with Les Laboratories Servier and Institut de Recherches Servier, or collectively Servier.

Recent Developments

Analysis of Data from Global Primary Biliary Cirrhosis Study Group

We are sponsoring an independent study currently involving a group of 15 academic medical centers from eight countries, collectively known as the Global PBC Study Group, or the Study Group, that are pooling their historical patient data to investigate the relationship between biochemical indicators of liver function and clinical outcomes in primary biliary cirrhosis. The data collection and analysis is being conducted independently at Erasmus University Medical Centre in Rotterdam, The Netherlands. We anticipate final data from at least 4,000 patients will be collected and analyzed as part of the study.

In April 2013, the Study Group presented an analysis of data from over 2,100 PBC patients, among whom 981 patients would have met one of the entry criteria for our ongoing Phase 3 POISE trial of having an alkaline phosphatase, or ALP, level exceeding 1.67 times upper limit normal, or ULN, and/or an abnormal bilirubin level. We believe that the analysis of this subgroup of patients from the Study Group further substantiates the primary endpoint used in POISE as being strongly predictive of adverse clinical outcomes such as liver transplant and death in PBC patients.

The data (Figure 1) show that after one year of ursodiol therapy 58.7% of this subgroup of PBC patients (n=576/981) had an inadequate therapeutic response to ursodiol as defined by having failed to meet an endpoint identical to the primary endpoint in our ongoing POISE trial, or the POISE endpoint. The POISE endpoint is defined as the achievement of both an ALP level of less than 1.67 times ULN (with a minimum 15% reduction from baseline) together with a normal bilirubin level. In the ursodiol non-responder group, 30.0% of patients went on to require a liver transplant or die (n=173/576) as compared to 12.6% of patients in the ursodiol responder group (n=51/405), reflecting a 2.4-fold higher event rate for the ursodiol non-responders (p=4.5x10E-10).

In order to censor out deaths due to causes other than PBC-associated liver failure, the Study Group analyzed younger subgroups of patients who were under 65 years old (n=789) and under 60 years old (n=666) at the time they initiated ursodiol therapy (Figures 2 and 3) and also would have met the POISE trial entry criteria. In the under 65 subgroup, after one year of ursodiol therapy, 60.5% of patients (n=477/789) failed to meet the POISE endpoint and 28.9% of these patients went on to require a liver transplant or die (n=138/477) as compared to 8.7% of patients in the ursodiol responder group (n=27/312), reflecting a 3.3-fold higher event rate for the ursodiol non-responders (p=1x10E-7). In the under 60 subgroup, after one year of ursodiol therapy, 61.3% of patients (n=408/666) failed to meet the POISE endpoint and 26.2% of these patients went on to require a liver transplant or die (n=107/408) as compared to 7.4% of patients in the ursodiol responder group (n=19/258), reflecting a 3.6-fold higher event rate for the ursodiol non-responders (p=1x10E-7).

The event rate among the ursodiol responders in the under 65 and under 60 subgroups was, respectively, 30.9% and 41.3% lower than the event rate of the ursodiol responder group in the overall ursodiol-treated patient cohort that included older patients. We believe that this difference is likely due to the greater exclusion of mortality unrelated to PBC in the younger ursodiol-treated patient subgroups, resulting in even greater differentiation of the ursodiol responder and non-responder groups.

The following figures show the results of the analyses conducted by the Study Group as described above.

Figure 1 - All Ursodiol-Treated Patients Meeting POISE Entry Criteria (p=4.5x10E-10)

Figure 2 – Ursodiol-Treated Patients Meeting POISE Entry Criteria Under 65 Years of Age (p=1x10E-7)

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Figure 3 – Ursodiol-Treated Patients Meeting POISE Entry Criteria Under 60 Years of Age (p=1x10E-7)

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. In August 2011, we entered into a collaboration agreement with Servier for the discovery, research and development of bile acid-derived agonists, or substances that bind to receptors of cells and trigger responses by those cells, for a dedicated bile acid receptor called TGR5. Under the terms of the agreement, we received an up-front payment from Servier of $1.4 million. Servier may be required to pay us up to an aggregate amount of approximately €108 million (approximately $138 million as of March 31, 2013) upon the achievement of specified development, regulatory and commercial sale milestones, as well as royalties on sales, based on the successful outcome of the collaboration. For accounting purposes, the up-front payments from both transactions are recorded as deferred revenue and amortized over time. Through March 31, 2013, we recognized $4.7 million in license revenue for the relevant amortization of the two up-front payments and have not received any milestone payments related to these agreements. As the Servier up-front payment has been fully recognized as of the third quarter of 2012, no further revenue will be recognized in respect of such payment. 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, 2013, we have incurred approximately $76.3 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 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 agonists of the farnesoid X receptor, or FXR, 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 Ended March 31,	
	2012	2013
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 1,943	$ 2,845
INT-767	—	85
INT-777	12	44
Total direct research and development expense	1,955	2,974
Personnel costs (1)	943	1,728
Indirect research and development expense	162	130
Total research and development expense	$ 3,060	$ 4,832

(1) Personnel costs include stock options and RSUs granted to employees and non-employees with an associated stock-based compensation expense of $154,000 and $709,000 for the three months ended March 31, 2012 and 2013, 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 Phase 3 clinical trial in patients with PBC, or POISE trial, and our other planned clinical and non-clinical studies and other work needed to submit OCA for the treatment of PBC for regulatory approval in the United States and Europe. We have incurred, and expect to continue to incur, significant expense in connection with these efforts, including:

- In January 2012, we initiated enrollment in our POISE trial, a Phase 3 clinical trial in patients with PBC, and we completed patient enrollment in December 2012. We currently expect results from the trial to be available in the second quarter of 2014. Patients who complete twelve months of treatment will be eligible to continue in an open label safety extension trial for five years. In March 2013, we enrolled our first patient into the long-term safety extension phase of our POISE trial.

- We continue to treat PBC patients from our Phase 2 trial with OCA as a monotherapy in a long-term safety extension trial. As of April 30, 2013, there were 19 patients being followed in this trial and we anticipate the trial to continue through 2015.

- We are currently dosing both mice and rats to investigate the carcinogenic potential of OCA. We anticipate dosing will be completed in the first quarter of 2014.

- We plan to initiate a Phase 2 clinical trial evaluating the potential effects and clinical significance of OCA on the lipid profile of patients with PBC, 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 2013.

- 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.

In addition, we are evaluating OCA in other chronic liver and other diseases. In connection with these efforts, we have incurred significant expenses relating to our agreement with the National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, for milestones related to the FLINT trial, a Phase 2b clinical trial in patients with nonalcoholic steatohepatitis, or NASH. These expenses include $1.0 million that was paid in June 2012 and an additional $1.25 million that was paid in connection with the full enrollment of the FLINT trial, which occurred on November 12, 2012. No further payments remain under the contract.

INT-767 and INT-777

We are currently conducting research in collaboration with Servier to discover and develop additional novel TGR5 agonists. We intend to continue to develop our two existing compounds not included in this collaboration, our dual FXR/TGR5 agonist INT-767 through preclinical development and, if warranted, Phase 1 clinical trials and INT-777 through potential collaborations with third parties, over the next several years.

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. General and administrative expense includes stock-based compensation expense of $238,000 and $898,000 for the three month periods ending March 31, 2012 and 2013, respectively. Other significant general and administrative expenses include allocation of facilities costs, professional fees for directors, accounting and legal services and expenses associated with obtaining and maintaining patents.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and due to activities related to the potential commercialization of our product candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also incurred and will continue to incur increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

Other Income, Net

Other income consists of interest income earned on our cash, cash equivalents and investment securities, offset by interest expense pertaining to equipment previously under a capitalized lease. This capitalized lease matured in 2012 and, as such, we will no longer be subject to the interest expense under this capitalized lease. We expect interest income to increase in future periods as we invest the proceeds from our preferred stock financings and initial public offering.

Revaluation of Warrants

In conjunction with various financing transactions, we issued warrants to purchase shares of our common stock. Certain of the warrants include a 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 applicable per share warrant exercise price. The warrants containing this provision are deemed to be derivative instruments and as such, are recorded as a liability and marked-to-market at each reporting period. Our remaining warrants include a provision that requires 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 are 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. We will continue to adjust the fair value of the common stock warrant liability at the end of each reporting period for changes in fair values until the earlier of the exercise or expiration of the applicable common stock warrants or until such time that the warrants are no longer determined to be derivative instruments. Because our common stock is publicly traded, these fluctuations are expected to increase or decrease significantly based on changes in the price of our common stock.

Results of Operations

Comparison of the Three Months Ended March 31, 2012 and the Three Months Ended March 31, 2013

The following table summarizes our results of operations for each of the three months ended March 31, 2012 and 2013, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,		Dollar Change	% Change
	2012	2013		
	(In thousands)			
Licensing revenue	$ 759	$ 405	$ (354)	(46.6)%
Operating expenses:				
Research and development	3,060	4,832	1,772	57.9 %
General and administrative	1,059	2,397	1,338	126.3 %
Loss from operations	(3,360)	(6,824)	(3,464)	103.1 %
Warrant revaluation income (expense)	678	(3,683)	(4,361)	*
Other income, net	2	296	294	*
Net loss	$ (2,680)	$ (10,211)	$ (7,531)	*

*Not meaningful or not calculable.

Licensing Revenue

Licensing revenue was $759,000 and $405,000 for the three months ended March 31, 2012 and 2013, respectively, resulting from the amortization of the up-front payments from the collaboration agreements entered into with DSP and Servier in 2011. The revenue for the three months ended March 31, 2013 is solely related to the DSP collaboration agreement. As the Servier up-front payment was fully recognized as of the third quarter of 2012, no further revenue will be recognized in respect of such payments.

Research and Development Expenses

Research and development expenses were $3.1 million and $4.8 million for the three months ended March 31, 2012 and 2013, respectively, representing an increase of $1.8 million or 57.9%. This increase in research and development expense primarily reflects:

- increased stock–based compensation expense of approximately $555,000;
- increased direct development expense for our Phase 3 POISE trial of approximately $423,000;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased cash compensation expense of approximately $218,000 and associated overhead of approximately $22,000;
- increased costs to validate an additional manufacturer of OCA and to manufacture our initial starting materials and clinical trial supplies of approximately $181,000;
- increased direct development expense for reproduction toxicology studies of approximately $122,000;
- increased costs for the preparation of our anticipated NDA and MAA filings of approximately $107,000; and
- increased costs associated with INT-767 IND enabling studies of approximately $85,000.

General and Administrative Expenses

General and administrative expenses were $1.1 million and $2.4 million in the three months ended March 31, 2012 and 2013, respectively. The $1.3 million increase primarily reflects:

- An increase in stock-based compensation expense of approximately $660,000;
- an increase in personnel to manage the increased activities due to our operating as a public company, resulting in increased cash compensation expense of approximately $157,000 and associated overhead of approximately $27,000;
- an increase in directors’ and officers’ insurance of approximately $129,000;
- an increase in expenses related to compensation consulting of approximately $106,000;
-

an increase in expenses related to the preparation and filing of our annual financial statements of approximately $88,000; and

- an increase in legal and security listing expenses of $170,000 to support our public company operations, offset by a decrease in patent fees of approximately $48,000.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the proceeds from our Series C preferred stock financing in August 2012 and our IPO in October 2012.

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 gain of $678,000 and a loss of $3.7 million for the three months ended March 31, 2012 and 2013, respectively. These fluctuations in value were primarily due to the declines in the estimated life of the warrants and changes in volatility of the shares of common stock underlying the warrants. For the three months ended March 31, 2013, the fair value was also affected by the increase in the price of the common stock underlying the warrants. Because our common stock is publicly traded, these fluctuations are expected to increase or decrease significantly based on changes in the price of our common stock.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since our inception in September 2002 and, as of March 31, 2013, we had an accumulated deficit of $128.4 million. 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, we have funded our operations principally with $181.5 million (net of issuance costs of $9.9 million) from the sale of common stock, preferred stock, convertible notes and warrants, including $29.7 in net proceeds from our Series C financing in August 2012 and $78.7 million in net proceeds from our initial public offering in October 2012, 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, 2013, we had cash, cash equivalents and investment securities of approximately $104.2 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.

Cash Flows

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

	Three Months Ended March 31,	
	2012	2013
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (3,893)	$ (5,636)
Investing activities	(24)	(8,252)
Financing activities	(58)	87
Effect of exchange rate changes	13	-
Net decrease in cash and cash equivalents	$ (3,962)	$ (13,801)

Operating Activities. Net cash used in operating activities of $3.9 million during the three month period ended March 31, 2012 was primarily a result of our $2.7 million net loss, partially offset by non-cash items consisting of stock-based compensation of $392,000, warrant liability revaluation income of $678,000 and net changes in operating assets and liabilities of $1.0 million. The change in operating assets and liabilities include an increase in prepaid expenses and other current assets of $232,000 and a decrease in deferred revenue of $759,000. The decrease in deferred revenue is due to the recognition of a portion of the up-front license payments received as part of our license agreements with DSP and Servier. 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.

Investing Activities. Net cash used in investing activities during the three months ended March 31, 2013 is primarily related to the investment of our available operating capital in marketable securities, which increased compared to the prior year period as a result of the proceeds from our Series C preferred stock financing in August 2012 and our IPO in October 2012.

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 current operating plan, we believe that our existing cash, cash equivalents, short-term investments and anticipated funding under our DSP and Servier collaborations will enable us to fund our operating expenses and capital expenditure requirements through mid-2015. This estimate reflects our ongoing POISE trial; nonclinical studies and clinical trials to support our planned regulatory submissions for OCA in PBC; and anticipated pre-commercial activities for OCA in PBC. 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.

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

- the progress, costs, results and timing of our POISE trial, and the clinical development of OCA for other potential indications;
- the willingness of the FDA and the European Medicines Agency, or 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 approval of OCA for PBC;
- 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;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities;

- the costs associated with securing and establishing commercialization and manufacturing capabilities;

- the costs of acquiring, licensing or investing in businesses, 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 other intellectual property rights;

- our need and ability to hire additional management and scientific and medical personnel;

- the effect of competing technological and market developments;

- our need to implement additional internal systems and infrastructure, including financial, reporting and security systems; and

- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements 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 April 1, 2013.

In April 2013, we extended our sponsored research agreement with the University of Perugia to research and develop improvements to the process for synthesizing and supplying gram scale reference standard quantities of OCA, INT-767 and INT-777 and the related consulting and intellectual property agreement with Professor Roberto Pellicciari. Each of the extensions became effective as of January 1, 2013 and the University of Perugia and Professor Pellicciari will continue to provide services under their respective agreements until December 31, 2013. During the extension period, we are required to pay the University of Perugia and Professor Pellicciari an aggregate of €80,000 and €100,000, respectively.

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 April 1, 2013.

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, 2013, 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.

We are not currently a party to any legal proceedings.

Item 1A. Risk Factors.

Other than as discussed below, 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, 2012. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in our Annual Report on Form 10-K.

Risks Relating to Owning Our Common Stock

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Global Market.

The trading market in our common stock is substantially less liquid than the average trading market for companies quoted on the NASDAQ Global Market. The quotation of our common stock on the NASDAQ Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of May 1, 2013, approximately 58.0% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC and its affiliates) and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

Our share price may be volatile, which could subject us to securities class action litigation and result in substantial losses to our stockholders.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in October 2012, the price of our common stock on the NASDAQ Global Market has ranged from $17.96 per share to $42.67 per share. In addition to the factors discussed in this "Risk Factors" section and in our Annual Report on Form 10-K, these factors include:

- adverse results or delays in our clinical trials;
- inability to obtain additional funding;
- any delay in filing an IND, NDA, MAA or comparable submission for any of our future product candidates and any adverse development or perceived adverse development with respect to the regulatory review of such submission;
- failure to successfully develop and commercialize OCA and any of our future product candidates;
- failure to maintain our existing strategic alliances or enter into new alliances;
- failure of our strategic alliance partners to elect to develop and commercialize product candidates under our alliance agreements or the termination of any programs under our alliance agreements;
- inability to obtain adequate product supply for OCA and our future product candidates or the inability to do so at acceptable prices;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- changes in laws or regulations applicable to our future products;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional financing efforts;
- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us, our insiders or our other stockholders;
- failure to adopt appropriate information security systems;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations may negatively impact the market price of shares of our common stock, regardless of our actual operating performance. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. As a result of this volatility, our stockholders could incur substantial losses.

We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest.

Genextra S.p.A., together with its affiliates, whom we refer to collectively as Genextra, is our largest stockholder. As of May 1, 2013, Genextra owned 7,187,217 shares of our common stock and warrants to purchase an additional 865,381 shares of our common stock. The shares of common stock owned by Genextra represented approximately 42.8% of our outstanding common stock. Accordingly, Genextra exerts significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors, amendments to our organizational documents, such as increases in our authorized shares of common stock, and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, if Genextra obtains a majority of our common stock, Genextra would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Genextra would be able to control the election of directors, amendments to our organizational documents and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if Genextra obtains a majority of our common stock, we would be deemed a “controlled company” for purposes of NASDAQ listing requirements. Under NASDAQ rules, a “controlled company” may elect not to comply with certain NASDAQ corporate governance requirements, including (i) the requirement that a majority of our board of directors consist of independent directors, (ii) the requirement that the compensation of our officers be determined or recommended to the board by a majority of independent directors or a compensation committee that is composed entirely of independent directors, and (iii) the requirement that director nominees be selected or recommended to the board by a majority of independent directors or a nominating committee that is composed of entirely independent directors.

Furthermore, the interests of Genextra may not always coincide with your interests or the interests of other stockholders and Genextra may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, and might affect the prevailing market price for our common stock. Our board of directors, which consists of seven directors, including two affiliated with Genextra, has the power to set the number of directors on our board from time to time.

Being a public company will increase our expenses and administrative burden.

As a public company, we are incurring, and will continue to incur, significant legal, insurance, accounting and other expenses. In addition, our administrative staff is required to perform additional tasks and we are required to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, laws, regulations and standards applicable to public companies relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the Securities and Exchange Commission and the NASDAQ Stock Market, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. For example, the NASDAQ Stock Market recently proposed rules that would require listed companies to maintain an internal audit function. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with our initial public offering, we increased our directors' and officers' insurance coverage, which increased our insurance cost. In the future, it may be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies, could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we have and intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we have and may continue to rely on these exemptions. If some investors find our common stock

less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) December 31, 2017; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10-K for the year ending December 31, 2013, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company, as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ, the Securities and Exchange Commission or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and not be detected.

A significant portion of our total outstanding shares of common stock is restricted from resale. The sale of these shares could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell

shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

As of May 1, 2013, we had 16,805,107 shares of common stock outstanding. Of these shares, an aggregate of 9,747,637 shares of our common stock, or 58.0% of our outstanding shares, were held by our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC and its affiliates) and their respective affiliates, which may be sold subject to Rule 144. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

In addition, as of May 1, 2013, holders of an aggregate of 10,548,404 shares of our common stock, including shares underlying warrants of such holders, have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all 2,712,103 shares of common stock that we may issue under our equity compensation plans and, as such, they can be freely sold in the public market upon issuance and once vested. Any sales of securities by these stockholders, option holders and warrant holders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plans and our outstanding warrants could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2012 Equity Incentive Plan, or the 2012 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. As of May 1, 2013, we had outstanding options to purchase 1,551,493 shares and restricted stock units for 141,360 shares of common stock. Furthermore, as of such date, 889,621 were reserved for future issuance under the 2012 Plan. Sales of shares granted under our equity incentive plans or upon exercise of warrants may result in material dilution to our existing stockholders, which could cause our share price to fall.

The number of shares available for future grant under the 2012 Plan will automatically increase each year by up to 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our

board of directors to take action to reduce the size of the increase in any given year. In April 2013, we registered the 661,075 additional shares of common stock that were added to the 2012 Plan on January 1, 2013 under this provision. We plan to register the increased number of shares available for issuance under the 2012 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

NASDAQ may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

If we fail to maintain the listing of our common stock on the NASDAQ Global Market, the liquidity for our common stock would be significantly impaired, which may substantially decrease the trading price of our common stock. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on NASDAQ. If NASDAQ delists our common stock from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of "blank check" convertible preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders, to the extent that no stockholder, together with its affiliates, holds more than 50% of our voting stock;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding equity awards upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the Delaware General Corporation Law, our restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the Delaware General Corporation Law, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification. If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action (*i.e.*, one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into indemnification agreements with each of our officers and directors.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we have increased the coverage under our directors' and officers' liability insurance, certain

liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the market price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2012 and March 31, 2013, we had federal net operating loss carryforwards, or NOLs, of $70.2 million and $75.5 million, respectively, which expire from 2024 through 2032. Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). We have assessed whether one or more ownership changes as defined under Section 382 have occurred since our inception and have determined that there have been at least two such changes. Accordingly, although we believe that these ownership changes have not resulted in material limitations on our ability to use these NOLs, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

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, 2013 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, 2013, we issued an aggregate of 98,427 shares of common stock upon exercise of previously issued and outstanding warrants to purchase common stock, all of which were issued upon the cashless exercise of such warrants. 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. Each of the purchasers in these transactions 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. Each purchaser 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.

As of March 31, 2013, the net proceeds from the offering were invested in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as commercial paper and corporate debt securities and U.S. government securities. 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.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

Amended and Restated Employment Agreements

On May 14, 2013, we entered into amended and restated employment agreements with Mark Pruzanski, President and Chief Executive Officer, David Shapiro, Chief Medical Officer and Executive Vice President—Development, Barbara Duncan, Chief Financial Officer, and Daniel Regan, Chief Commercial Officer, and entered into an amended and restated consulting agreement with Luciano Adorini, Chief Scientific Officer. A copy of each of the amended and restated agreements are filed as exhibits to this Form 10-Q, and are incorporated by reference herein.

Descriptions of the employment agreements of Dr. Pruzanski, Dr. Shapiro and Ms. Duncan, our named executive officers, are set forth below. The following descriptions are qualified in their entirety by reference to the amended and restated employment agreements filed herewith.

Mark Pruzanski, M.D. On May 14, 2013, we entered into an amended and restated employment agreement with Dr. Pruzanski, our President and Chief Executive Officer. His employment agreement provides for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Dr. Pruzanski. Dr. Pruzanski's base salary, effective as of April 1, 2013, is set at $500,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Dr. Pruzanski's employment agreement also provides that he is eligible to receive an annual bonus payment of up to 50% of his annual base salary, based on achievement of certain performance milestones identified by our board of directors in consultation with Dr. Pruzanski.

Dr. Pruzanski is also eligible to participate in our group benefits programs, including but not limited to medical, disability and life insurance, vacation and retirement plans, and a 401(k) plan sponsored by us. We have agreed to pay 100% of the health insurance premiums of Dr. Pruzanski and his spouse and other dependents and an annual life insurance premium of $10,000. During 2012, although we paid the premium for Dr. Pruzanski's participation in our group life insurance policy, which is available generally to all employees, we did not purchase or pay premiums for any individual life insurance policy for Dr. Pruzanski. We are also required to purchase short-term and long-term disability policies insuring at least 60% of Dr. Pruzanski's base salary.

If Dr. Pruzanski terminates his employment with us or we terminate his employment for any reason, in addition to payment of accrued compensation and benefits, Dr. Pruzanski will be entitled to an amount equal to his target bonus for the prior year, if unpaid, and the prorated portion of his target bonus for the year in which his termination occurs.

In the event we do not renew Dr. Pruzanski's employment at the end of the employment term, Dr. Pruzanski is terminated by us without cause, as defined in the employment agreement, or he resigns with good reason, as defined in the employment agreement, Dr. Pruzanski will be entitled to receive (i) 12 months of his base salary payable according to our company's payroll, (ii) a lump sum payment equal to the mean bonus earned by him during the prior three years (such payment shall be in lieu of the prorated bonus payment for the year in which the termination occurs described above) and (iii) continuation of participation in our group health and/or dental plan and the payment of his premiums for 12 months from the date of termination (or the cost of COBRA coverage for such period) for Dr. Pruzanski, his spouse and any dependents covered under our group health and/or dental plan prior to termination.

In the event that Dr. Pruzanski does not renew his employment at the end of the employment term, is terminated for cause, is terminated due to death or disability, or he terminates his employment without good reason, Dr. Pruzanski will not be entitled to any severance benefits except as otherwise described below or mutually agreed upon in writing. If Dr. Pruzanski is terminated due to disability, he is entitled to (i) 12 months of base salary payable according to our company's payroll, so long as he is not eligible to participate in a company-sponsored short-term and long-term disability plans that provide for benefits of at least 60% of base salary, and (ii) continued participation in our group health and/or dental plan and the payment of his premiums for 12 months following the date of termination (or the cost of COBRA coverage for such period) for Dr. Pruzanski, his spouse and any dependents covered under our group health and/or dental plan prior to termination.

If we do not renew Dr. Pruzanski's employment at the end of the employment term, Dr. Pruzanski is terminated by us without cause, he resigns with good reason or Dr. Pruzanski is terminated due to his death or disability, all of Dr. Pruzanski's stock options and equity awards granted after the date of his employment agreement will vest immediately and his stock options will be exercisable for three years from the effective date of termination. In the event that Dr. Pruzanski does not renew his employment at the end of the employment term, Dr. Pruzanski is terminated for cause or he terminates his employment without good reason, all of his unvested equity awards and stock options will immediately be forfeited and all of his vested stock options will be exercisable for three years from the effective date of termination. The above provisions in Dr. Pruzanski's employment agreement relating to the vesting of equity awards are in addition to the vesting provisions contained in our equity incentive plans.

In the event of the termination of Dr. Pruzanski's employment in anticipation of, and/or within three months before or 12 months following, a change in control, as defined in the employment agreement, (i) by us because we do not renew Dr. Pruzanski's employment at the end of the employment term, (ii) by us for any reason other than for cause or (iii) by Dr. Pruzanski for good reason, Dr. Pruzanski will be entitled to receive (a) an amount equal to 24 months' of his then-current monthly base salary payable as a single lump sum, (b) a lump sum payment equal to two times the mean bonus earned during the prior three years (such payment shall be in lieu of the prorated bonus payment for the year in which the termination occurs described above) and (c) continuation of participation in our group health and/or dental plan and the payment of his premiums for up to 24 (but not less than 18) months from the date of termination (or the cost of COBRA coverage for such period) for Dr. Pruzanski, his spouse and any dependents covered under our group health and/or dental plan prior to termination.

Receipt of the severance benefits described above is conditioned upon Dr. Pruzanski entering into a release of claims with us and the release becoming effective and irrevocable within 60 days after termination. Dr. Pruzanski has acknowledged and agreed that the timing of payments may be modified by us to comply with Section 409A of the Internal Revenue Code of 1986, as amended, or the Code.

To the extent that we are required to implement a clawback policy for the incentive compensation paid to Dr. Pruzanski based on erroneous data contained in an accounting statement pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Dr. Pruzanski's employment agreement contemplates that the terms of such policy will be incorporated into his employment agreement, provided that such policy applies to the other executive officers of our company.

Under Dr. Pruzanski's employment agreement, "cause" for termination shall be deemed to exist upon (a) a good faith finding by a majority of the members of the board (excluding Dr. Pruzanski) that (i) Dr. Pruzanski has engaged in material dishonesty, willful misconduct or gross negligence, or (ii) Dr. Pruzanski has materially breached the employment agreement, and has failed to cure such conduct or breach within 30 days after his receipt of written notice from us, or (b) Dr. Pruzanski's conviction or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony. Under Dr. Pruzanski's employment agreement, "good reason" is defined as a material

change in duties, position, responsibilities or reporting requirements, relocation of Dr. Pruzanski's place of employment by more than 50 miles from his principal residence or place of employment prior to such change or our material breach of the employment agreement.

David Shapiro, M.D. On May 14, 2013, we entered into an amended and restated employment agreement with Dr. Shapiro, our Chief Medical Officer and Executive Vice President, Development. This employment agreement provides for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Dr. Shapiro. Dr. Shapiro's base salary, effective as of April 1, 2013, is set at $380,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Dr. Shapiro is also eligible to receive an annual bonus payment of up to 35% of his annual base salary, based on achievement of certain performance milestones identified by our board of directors in consultation with Dr. Shapiro and our chief executive officer.

Dr. Shapiro is also eligible to participate in our group benefits programs, including but not limited to medical, disability and life insurance, vacation and retirement plans, and a 401(k) plan sponsored by us. We have agreed to provide Dr. Shapiro with a monthly car allowance of $1,000 and to pay 100% of the health insurance premiums of Dr. Shapiro and his spouse and children, if his spouse and dependents are not already covered by the health insurance plan of his spouse's employer.

In the event we do not renew Dr. Shapiro's employment at the end of the employment term, Dr. Shapiro is terminated by us without cause, as defined in the employment agreement, or he resigns with good reason, as defined in the employment agreement, Dr. Shapiro will be entitled to receive (i) 12 months of his base salary paid in a single lump sum and (ii) continuation of participation in our group health and/or dental plan and the payment of his premiums for 12 months (or the cost of COBRA coverage for such period) for Dr. Shapiro and his dependents covered under our group health and/or dental plan prior to termination. In the event that Dr. Shapiro does not renew his employment at the end of the employment term, is terminated for cause, is terminated due to death or disability, or he terminates his employment without good reason, Dr. Shapiro will not be entitled to severance payments unless mutually agreed upon in writing.

If we do not renew Dr. Shapiro's employment at the end of the employment term, Dr. Shapiro is terminated by us without cause or he resigns with good reason, all of Dr. Shapiro's equity awards and stock options that would have vested within one year of the termination date will vest immediately and all vested stock options will be exercisable for one year from the effective date of termination. In the event that Dr, Shapiro is terminated for cause or he terminates his employment without good reason, all unvested equity awards and stock options granted will immediately be forfeited.

In the event of the termination of Dr. Shapiro's employment in anticipation of, and/or within 12 months following, a change in control (i) by us because we do not renew Dr. Shapiro's employment at the end of the employment term, (ii) by us for any reason other than for cause or (iii) by Dr. Shapiro for good reason, Dr. Shapiro will be entitled to receive (a) an amount equal to 12 months of his then-current monthly base salary payable as a single lump sum and (b) continuation of participation in our group health and/or dental plan and the payment of his premiums for 12 months (or the cost of COBRA coverage for such period) for Dr. Shapiro, his spouse and any dependents covered under our group health and/or dental plan prior to termination. In such instances of termination, all of Dr. Shapiro's unvested equity awards and stock options will immediately become fully vested and all of his vested stock options will be exercisable for a period of one year following the effective date of termination. This provision in Dr. Shapiro's employment agreement relating to the vesting of equity awards upon a change of control is in addition to the provisions contained in our equity incentive plans governing the vesting of equity awards upon a change of control.

Receipt of the severance benefits described above is conditioned upon Dr. Shapiro entering into a release of claims with us and the release becoming effective and irrevocable within 60 days after termination. Dr. Shapiro has acknowledged and agreed that the timing of payments may be modified by us to comply with Section 409A of the

Code.

To the extent that we are required to implement a clawback policy for the incentive compensation paid to Dr. Shapiro based on erroneous data contained in an accounting statement pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Dr. Shapiro's employment agreement contemplates that the terms of such policy will be incorporated into his employment agreement, provided that such policy applies to the other executive officers of our company.

Under Dr. Shapiro's employment agreement, "cause" for termination shall be deemed to exist upon (a) a good faith finding by us that (i) Dr. Shapiro has engaged in material dishonesty, willful misconduct or gross negligence, (ii) Dr. Shapiro has materially breached the employment agreement, or (iii) Dr. Shapiro has breached or threatened to breach his invention, non-disclosure and non-solicitation agreement, and has failed to cure such conduct or breach within 30 days after his receipt of written notice from us, or (b) Dr. Shapiro's conviction or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony. Under Dr. Shapiro's employment agreement, "good reason" is defined as a material change in duties, position, responsibilities or reporting requirements, a relocation of Dr. Shapiro's place of employment by more than 50 miles from his principal residence or place of employment immediately prior to such change or our material breach of the employment agreement.

Barbara Duncan. On May 14, 2013, we entered into an amended and restated employment agreement with Ms. Duncan, our Chief Financial Officer, which was amended on April 12, 2013. Ms. Duncan's employment agreement provides for an initial term of one year with automatic renewals each year thereafter unless terminated by either us or Ms. Duncan. Ms. Duncan's base salary, effective as of April 1, 2013, is set at $335,000 per year, subject to annual review and increase (but not decrease), as determined by our board of directors or the compensation committee. Ms. Duncan is also eligible to receive an annual bonus payment of up to 35% of her annual base salary, based on achievement of certain performance milestones identified by our board of directors in consultation with Ms. Duncan and our chief executive officer.

Ms. Duncan is also eligible to participate in our group benefits programs, including but not limited to medical, disability and life insurance, vacation and retirement plans, and a 401(k) plan sponsored by us. We have agreed to pay 100% of the health insurance premiums of Ms. Duncan and her spouse and children, so long as they are not covered by the policy of her spouse's employer.

In the event we do not renew Ms. Duncan's employment at the end of the employment term, Ms. Duncan is terminated by us without cause, as defined in the employment agreement, or she resigns with good reason, as defined in the employment agreement, Ms. Duncan will be entitled to receive (i) 12 months of her base salary payable according to our company's payroll and (ii) continuation of her participation in our group health and/or dental plan and the payment of her premiums for 12 months (or the cost of COBRA coverage for such period) for Ms. Duncan and her dependents covered under our group health and/or dental plan prior to termination. In the event that Ms. Duncan does not renew her employment at the end of the employment term, is terminated for cause, or is terminated due to her death or disability or she terminates her employment without good reason, Ms. Duncan will not be entitled to any severance benefits unless mutually agreed upon in writing.

If we do not renew Ms. Duncan's employment at the end of the employment term, Ms. Duncan is terminated by us without cause or Ms. Duncan resigns with good reason, all of Ms. Duncan's equity awards and stock options that would have vested within one year of the termination date will vest immediately and all vested stock options will be exercisable for one year from the effective date of termination. If Ms. Duncan's employment is terminated due to disability, all unvested equity awards and stock options will be forfeited and she will be able to exercise her vested options for one year from the date of termination. In the event that Ms. Duncan is terminated for cause or she terminates her employment without good reason, all unvested equity awards and stock options granted will immediately be forfeited.

In the event of the termination of Ms. Duncan's employment in anticipation of, and/or within 12 months following, a change in control (i) by us because we do not renew Ms. Duncan's employment at the end of the employment term, (ii) by us for any reason other than for cause or (iii) by Ms. Duncan for good reason, Ms. Duncan will be entitled to receive (a) an amount equal to 12 months of her then-current monthly base salary payable as a single lump sum and (b) continuation of her participation in our group health and/or dental plan and the payment of her premiums for 12

months (or the cost of COBRA coverage for such period) for Ms. Duncan, her spouse and any dependents covered under our group health and/or dental plan prior to termination. In such instances of termination, all of Ms. Duncan's unvested equity awards and stock options granted will immediately become fully vested and all of her vested stock options will be exercisable for a period of one year following the effective date of termination. This provision in Ms. Duncan's employment agreement relating to the vesting of equity awards upon a change of control is in addition to the provisions contained in our equity incentive plans governing the vesting of equity awards upon a change of control.

Receipt of the severance benefits described above is conditioned upon Ms. Duncan entering into a release of claims with us and the release becoming effective and irrevocable within 60 days after termination. Ms. Duncan has acknowledged and agreed that the timing of payments may be modified by us to comply with Section 409A of the Code.

To the extent that we are required to implement a clawback policy for the incentive compensation paid to Ms. Duncan based on erroneous data contained in an accounting statement pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Ms. Duncan's employment agreement contemplates that the terms of such policy will be incorporated into her employment agreement, provided that such policy applies to the other executive officers of our company.

Under Ms. Duncan's employment agreement, "cause" for termination shall be deemed to exist upon (a) a good faith finding by us that (i) Ms. Duncan has engaged in material dishonesty, willful misconduct or gross negligence, (ii) Ms. Duncan has materially breached the employment agreement, or (iii) Ms. Duncan has breached or threatened to breach her invention, non-disclosure and non-solicitation agreement, and has failed to cure such conduct or breach within 30 days after her receipt of written notice from us, or (b) Ms. Duncan's conviction or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony. Under Ms. Duncan's employment agreement, "good reason" is defined as a material diminution in duties, position, responsibilities or reporting requirements, relocation of Ms. Duncan's place of employment by more than 50 miles from her principal residence or place of employment immediately prior to such relocation or a material breach of the employment agreement by us.

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 14, 2013 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2013 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index.

Exhibit Number	Description of Exhibit
10.1	First Amendment to Lease Agreement between 4350 La Jolla Village LLC and the Registrant, dated March 18, 2013 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on March 22, 2013).
10.2	Amendment No. 2 to the Servier Agreement, dated February 15, 2013 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on February 22, 2013).*
10.3	Amendment No. 2 to Consulting and IP Agreement with Professor Roberto Pellicciari, dated February 15, 2013 (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on February 22, 2013).*
10.4	Amendment No. 2 to the TES Agreement, dated February 15, 2013 (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed on February 22, 2013).*
10.5	Amended and Restated Employment Agreement by and between the Registrant and Mark Pruzanski, dated May 14, 2013.#
10.6	Employment Agreement by and between the Registrant and Daniel Regan, effective as of March 4, 2013 (incorporated by reference to Exhibit 10.7.1 to Registrant's Annual Report on Form 10-K filed on April 1, 2013).#
10.7	Invention, Non-Disclosure, and Non-Solicitation Agreement by and between the Registrant and Daniel Regan, dated March 4, 2013 (incorporated by reference to Exhibit 10.7.2 to Registrant's Annual Report on Form 10-K filed on April 1, 2013).#
10.8	Amendment to Employment Agreement by and between Registrant and Daniel Regan, dated April 12, 2013 (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on April 15, 2013).#
10.9	Amended and Restated Employment Agreement by and between Registrant and Daniel Regan, dated May 14, 2013.#
10.10	Amendment to Employment Agreement by and between Registrant and Barbara Duncan, dated April 12, 2013 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on April 15, 2013).#
10.11	Amended and Restated Employment Agreement by and between the Registrant and David Shapiro, dated May 14, 2013.#
10.12	

	Amended and Restated Employment Agreement by and between the Registrant and Barbara Duncan, dated May 14, 2013.#
10.13	Amended and Restated Consulting Agreement by and between the Registrant and Luciano Adorini, dated May 14, 2013 #
10.14	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on May 13, 2013).#
10.15	Amendment No. 1 to Sponsored Research Agreement between Registrant, Dipartimento di Chimica e Tecnologia del Farmaco of the Universitá di Perugia, and Professor Roberto Pellicciari, dated April 29, 2013 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on April 30, 2013).
10.16	Amendment No. 1 to Consulting and IP Agreement by and between Registrant and Roberto Pellicciari, dated April 29, 2013 (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K filed on April 30, 2013).
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, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2012 and March 31, 2013 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month periods ended March 31, 2012 and 2013 (unaudited), and the period from September 4, 2002 (inception) through March 31, 2013 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2012 and 2013 (unaudited) and for the period from September 4, 2002 (inception) to March 31, 2013 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited).+

* Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.
# 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.