

INTERCEPT PHARMACEUTICALS INC  
Form 10-Q  
November 14, 2013

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2013**

**OR**

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

**For the transition period from                      to**

**Commission file number: 001-35668**

**INTERCEPT PHARMACEUTICALS, INC.  
(Exact Name of Registrant as Specified in Its Charter)**

**Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)**

**22-3868459  
(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 ☒ 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

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to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	(Do not check if a smaller reporting company)	
		Smaller reporting company	<input type="checkbox"/>

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

As of October 31, 2013, there were 19,335,576 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,” “potential,” “will,” “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:

- our estimates regarding expenses, future revenues and capital requirements;
- 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 initial public offering in October 2012 and our follow-on public offering in June 2013;
- 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2013, particularly in Item 1A. Risk Factors, and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, 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)	September 30, 2013 (Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 45,511,641	\$ 33,492,017
Investment securities, available-for-sale	64,682,270	123,260,775
Prepaid expenses and other current assets	1,584,308	1,601,213
Total current assets	111,778,219	158,354,005
Fixed assets, net	148,838	190,673
Security deposits	251,540	346,611
Total assets	\$ 112,178,597	\$ 158,891,289
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	\$ 3,745,773	\$ 5,079,581
Short-term portion of warrant liability	7,596,659	809,867
Short-term portion of deferred revenue	1,621,622	1,621,622
Total current liabilities	12,964,054	7,511,070
Long-term liabilities:		
Long-term portion of warrant liability	22,762,135	51,093,479
Long-term portion of deferred revenue	10,540,543	9,324,324
Total liabilities	46,266,732	67,928,873
Stockholders' equity:		
Common stock. 25,000,000 shares authorized; 16,526,885 and 19,300,957 shares issued and outstanding as of December 31, 2012 and September 30, 2013, respectively; par value \$0.001 per share	16,527	19,301
Additional paid-in capital	184,100,139	264,519,497
Accumulated other comprehensive income (loss), net	(21,451)	31,106
Accumulated deficit during development stage	(118,183,350)	(173,607,488)
Total stockholders' equity	65,911,865	90,962,416
Total liabilities and stockholders' equity	\$ 112,178,597	\$ 158,891,289

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		Nine Months Ended		Period From
	September 30,		September 30,		September 4,
	2012	2013	2012	2013	2002
					(Inception)
					Through
					September 30,
					2013
Licensing revenue	\$ 523,191	\$ 405,407	\$ 2,040,700	\$ 1,216,219	\$ 5,467,454
Costs and expenses:					
Research and development	3,318,310	8,392,628	11,395,924	18,358,155	89,792,846
General and administrative	991,062	3,115,095	2,994,121	8,402,454	38,000,536
Total operating expenses	4,309,372	11,507,723	14,390,045	26,760,609	127,793,382
Other income (expense):					
Revaluation of warrants	(1,417,690)	(20,756,086)	(438,215)	(30,010,672)	(53,086,248)
Foreign currency loss on liquidation	-	-	(191,733)	-	(191,733)
Other income (expense), net	16,883	121,329	26,625	130,924	1,507,462
QTDP Grant	-	-	-	-	488,959
	(1,400,807)	(20,634,757)	(603,323)	(29,879,748)	(51,281,560)
Net loss	(5,186,988)	(31,737,073)	(12,952,668)	(55,424,138)	(173,607,488)
Dividends on preferred stock, not declared	(1,000,000)	-	(2,500,000)	-	(10,944,134)
Net loss attributable to common stockholders	\$ (6,186,988)	\$ (31,737,073)	\$ (15,452,668)	\$ (55,424,138)	\$ (184,551,622)
Net loss per share, basic and diluted	\$ (1.86)	\$ (1.65)	\$ (4.64)	\$ (3.15)	
Weighted average number of shares of common stock outstanding, basic and diluted:	3,329,266	19,198,923	3,329,266	17,585,531	
Other comprehensive gain/(loss):					
Unrealized gain / (loss) on investment securities	-	140,397	-	52,557	



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Foreign currency translation adjustments	-	-	184,500	-
Total comprehensive loss	\$ (5,186,988)	\$ (31,596,676)	\$ (12,768,168)	\$ (55,371,581)

See accompanying notes to the condensed consolidated financial statements.

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

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

	Nine Months Ended September		Period from
	30,	2013	September 4,
	2012		2002
			(Inception)
			Through
			September
			30, 2013
Cash flows from operating activities:			
Net loss	\$ (12,952,668)	\$ (55,424,138)	\$ (173,607,488)
Adjustments to reconcile net loss to net cash used in operating activities:			
Revaluation of warrants	438,215	30,010,672	53,086,248
Stock-based compensation	1,251,579	6,478,346	16,256,216
Amortization of investment premium	-	1,076,157	1,194,337
Depreciation & amortization	178,469	79,370	2,446,039
Foreign currency loss on liquidation	191,733	-	191,733
Loss from sale of assets	-	-	217,296
Impairment of bonds	-	-	151,402
Changes in:			
Prepaid expenses and other assets	(1,110,136)	80,900	(1,278,720)
Accounts payable, accrued expenses, and other current liabilities	2,586,275	1,333,808	5,079,585
Deferred revenue	(2,040,700)	(1,216,219)	10,945,946
Interest accrued on promissory notes	-	-	91,249
Net cash used in operating activities	(11,457,233)	(17,581,104)	(85,226,157)
Cash flows from investing activities:			
Investments in certificates of deposit	120,399	-	(627,631)
Purchases of investment securities	-	(86,231,665)	(152,172,641)
Sales of investment securities	-	26,436,682	27,555,757
Purchases of equipment, improvements, and furniture and fixtures	(24,112)	(121,205)	(1,518,443)
Net cash used in investing activities	96,287	(59,916,188)	(126,762,958)
Cash flows from financing activities:			
Proceeds from issuance of stock offerings, net of issuance costs	29,713,851	61,169,317	233,646,479
Proceeds from issuance of common stock warrants	-	-	7,385,897
Payments of capital lease obligation	(81,762)	-	(1,335,567)
Proceeds from exercise of options	-	4,300,250	4,342,955
Proceeds from exercise of warrants	-	8,101	383,101
Proceeds from issuance of convertible promissory notes payable	-	-	1,250,000
Net cash provided by financing activities	29,632,089	65,477,668	245,672,865
Effect of exchange rate changes	(7,233)	-	(191,733)

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Net increase (decrease) in cash and cash equivalents	18,263,910	(12,019,624)	33,492,017
Cash and cash equivalents beginning of period	17,707,476	45,511,641	-
Cash and cash equivalents end of period	\$ 35,971,386	\$ 33,492,017	\$ 33,492,017
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	\$ 4,232	\$ -	\$ 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	-	8,455,833	9,380,323

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 (a bile acid receptor) research through its collaboration with Les Laboratoires Servier and Institut de Recherches Servier, or collectively Servier. On March 15, 2013, the Company decided to remove the Italian subsidiary from the legal liquidation process, which removal was completed as of July 15, 2013, so that it could continue 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 for the year ended December 31, 2012 filed with the Securities and Exchange Commission on April 1, 2013. The results for the year ended December 31, 2012, the three and nine months ended September 30, 2012 and September 30, 2013

(unaudited), and for the period from inception (September 4, 2002) through September 30, 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. Summary of Significant Accounting Policies**

The Company's significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**3. 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.

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 September 30, 2012 and 2013, the Company recorded revenue of \$405,000 and \$405,000, respectively, and during the nine months ended September 30, 2012 and 2013, the Company recorded revenue of \$1,215,000 and \$1,216,000, respectively, in "Licensing Revenue" in its Consolidated Statement of Operations for the Company's efforts under the agreement. The Company has not achieved any of the milestones relating to the agreement as of September 30, 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 Laboratoires 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.

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 and nine months ended September 30, 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.

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

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 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 and nine months ended September 30, 2012, the Company recorded revenue of \$118,000 and \$824,000, respectively, 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 months and nine months ended September 30, 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.

The Company is required to conduct a research program under the agreement to identify and optimize compounds that meet certain specified criteria sufficient for further development by Servier. The Company has engaged Professor Pellicciari and TES Pharma SRL (TES) to provide the research services required under the agreement, as described below. Servier is required to reimburse the Company for the full time equivalent costs incurred by the Company in the conduct of the research program, up to a set maximum amount. The Company recognizes the expense reimbursement from Servier 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 and nine months ended September 30, 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 September 30, 2013, the Company recorded \$496,000 and \$507,000, respectively, in prepaid expenses and other assets for amounts due from Servier for such expense reimbursement.

The research portion of the collaboration may be extended by mutual agreement by the parties for one or more additional years. In July 2012, February 2013 and August 2013, the term of the research program was extended until January 31, 2013, July 31, 2013 and September 30, 2013, respectively, on the same financial terms as the existing research program, including the reimbursement by Servier. In November 2013, the Company and Servier further extended the research program until September 30, 2015 on the same financial terms as the existing agreement, with such extension being effective as of October 1, 2013.

***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 September 30, 2012 and 2013 of \$16,000 and \$26,000,



respectively, and for the nine months ended September 30, 2012 and 2013 of \$77,000 and \$80,000, 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 September 30, 2013. In July 2012, February 2013 and August 2013, by mutual agreement of the parties, the term of this agreement was extended until January 31, 2013, July 31, 2013 and September 30, 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. In November 2013, in conjunction with the extension of the research program with Servier, the parties further extended the consulting agreement until September 30, 2015 on the same financial terms as the original consulting agreement with Professor Pellicciari, with such extension being effective as of October 1, 2013.

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The Company recognized expense related to these agreements for the three months ended September 30, 2012 and 2013 of \$80,000 and \$68,000, respectively, and for the nine months ended September 30, 2012 and 2013 of \$243,000 and \$234,000, 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.

The agreement had 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, February 2013 and August 2013, by mutual agreement of the parties, the term of this agreement was extended until January 31, 2013, July 31, 2013, and September 30, 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.

In November 2013, in conjunction with the extension of the research program with Servier, the parties agreed to further extend the research agreement with TES until September 30, 2015, with such extension being effective as of October 1, 2013. Pursuant to the amended agreement, the Company is required to pay TES an aggregate amount of €250,000 on a quarterly basis during the extended term. The Company also agreed to provide TES with a low single digit royalty based on worldwide net sales of products developed under the agreement on a country-by-country basis. Royalty rates are subject to reduction under the agreement in specified circumstances, including with respect to any country if sales of generic products reach a certain threshold in that country.

The Company incurred charges related to this agreement for the three months ended September 30, 2012 and 2013 of \$310,000 and \$227,000, respectively, and \$982,000 and \$888,000 for the nine months ended September 30, 2012 and 2013, 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 to perform certain research and laboratory services. The agreement was amended in October 2011. The agreement has a term ending on

October 2, 2014, 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 September 30, 2012 and 2013 of \$345,000 and \$363,000, respectively, and for the nine months ended September 30, 2012 and 2013 of \$1.2 million and \$1.4 million, respectively.

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**4. Investments**

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2012 and September 30, 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

As of September 30, 2013				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
(In thousands)				
Cash and cash equivalents:				
Cash and money market funds	\$ 33,492	\$	\$	\$ 33,492
Investment securities:				
Commercial paper	4,998	1		4,999
Corporate debt securities	105,905	78	(28)	105,955
U.S. government and agency securities	11,237	10	-	11,247
Municipal government securities	1,061		(2)	1,059
Total investments	123,201	89	(30)	123,260
Total cash, cash equivalents and investments	\$ 156,693	\$ 89	\$ (30)	\$ 156,752

The following table shows the fair value and gross unrealized losses 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)
Available-for-sale securities	\$ 40,295	\$ (38)

As of September 30, 2013  
Less Than 12 Months

Fair Value	Gross Unrealized Holding Losses
------------	---------------------------------------

(In thousands)

Corporate debt securities	\$ 31,265	\$ (28)
Municipal government securities	1,059	(2)
Available-for-sale securities	\$ 32,324	(30)

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**5. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following:

	December 31, 2012 (In thousands)	September 30, 2013
Prepaid expenses	\$ 970	\$ 383
Contract receivable	496	514
Certificate of deposit	77	
Interest receivable		684
Other receivable		20
Refundable tax credits	42	
Prepaid expenses and other current assets	\$ 1,585	\$ 1,601

**6. Fixed Assets, Net**

Fixed assets, net consisted of the following:

	December 31, 2012 (In thousands)	September 30, 2013
Office equipment	\$ 357	\$ 396
Leasehold improvements	178	256
Furniture and fixtures under capitalized lease	157	157
Furniture and fixtures	121	125
Subtotal fixed assets	813	934
Less: accumulated depreciation and amortization	(664)	(743)
Fixed assets, net	\$ 149	\$ 191

Depreciation and amortization expense for the three months ended September 30, 2012 and 2013 was \$24,000 and \$27,000, respectively, and \$178,000 and \$79,000 for the nine months ended September 30, 2012 and 2013, respectively.

**7. Accounts Payable, Accrued Expenses and Other Liabilities**

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

	December 31, 2012 (In thousands)	September 30, 2013
Accounts payable	\$ 1,180	\$ 1,384

Accrued employee compensation	1,335	959
Accrued contracted services and other	1,231	2,737
Accounts payable, accrued expenses and other liabilities	\$ 3,746	\$ 5,080

**8.**

**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.

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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 realized. 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 September 30, 2013, the Company had available net operating loss carryforwards to reduce future taxable income of approximately \$70.2 million and \$97.6 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 \$52.1 million at December 31, 2012 and September 30, 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.

**9. 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 initial public offering (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, 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.

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 September 30, 2013, the Company had outstanding warrants to purchase a total of 878,201 shares of its common stock, at a weighted average exercise price of \$10.34 per share. Of these warrants, 8,494 expired in October 2013, 4,326 were converted into 3,852 shares of common stock upon “cashless” exercise in October 2013 and 865,381 will expire in January 2015, if not exercised. All of these warrants are “in the money” based on the market price of our common stock as of September 30, 2013.

#### **10. Fair Value Measurements**

The Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Financial assets and liabilities recorded at fair value on the Company’s consolidated balance sheets are categorized 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).

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The following table presents the Company's financial assets and liabilities, measured at fair value based on the hierarchy above:

	Total	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1) (In thousands)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
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 financial assets	\$ 89,543	\$ 24,862	\$ 64,681	\$
Liabilities:				
Warrants to purchase common stock	\$ (30,359)	\$	\$	\$ (30,359)
Total financial liabilities	\$ (30,359)	\$	\$	\$ (30,359)
September 30, 2013				
Assets:				
Money market funds	\$ 16,426	\$ 16,426	\$	\$
Available for sale securities:				
Commercial paper	\$ 4,999	\$	\$ 4,999	\$
Corporate debt securities	105,955		105,955	
U.S. government and agency securities	11,247		11,247	
Municipal securities	1,059		1,059	
Total financial assets	\$ 139,686	\$ 16,426	\$ 123,260	\$
Liabilities:				
Warrants to purchase common stock	\$ (51,903)	\$	\$	\$ (51,903)
Total financial liabilities	\$ (51,903)	\$	\$	\$ (51,903)



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***Level 3 Valuation***

Financial assets or liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The following table provides a summary of the changes in fair value of the Company's financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the nine-month period ended September 30, 2013.

	Warrant Liability (In thousands)
Level 3	
Balance at December 31, 2012	\$ 30,359
Losses recognized in earnings	30,011
Exercises	(8,467)
Balance at September 30, 2013	\$ 51,903

The Company determines the fair value of its warrant liability based on the Black-Scholes pricing model based on the Company's stock price at the measurement date, exercise price of the warrant, risk free interest rate and historical volatility.

The estimated fair values of marketable debt securities (commercial paper, corporate debt securities, U.S. government and agency securities, and municipal securities) as of September 30, 2013, by contractual maturity, are as follows:

	Fair Value (In thousands)
Due in one year or less	\$ 55,923
Due after one year through two years	67,337
Total investments in debt securities	\$ 123,260

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

**11. 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.

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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.

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

In May 2006, pursuant to a private placement agreement, the Company issued 2,087,091 shares of common stock at a price of \$9.82 per share, 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 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 offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's preferred stock (described below) were converted into 7,403,817 shares of common stock. Additionally, upon completion of the IPO, the Company is now authorized to issue 25,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share.

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

*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.

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**12. 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.

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 September 30, 2013, there were 470,714 shares of common stock authorized for future issuance under the 2012 Plan.

The following table summarizes stock option activity during the nine months ended September 30, 2013:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2012	1,526,150	\$ 10.67
Granted	522,950	35.14
Exercised	(505,173)	9.78
Forfeited	(8,589)	11.87
Outstanding, September 30, 2013	1,535,338	\$ 19.29
Exercisable, September 30, 2013	798,655	\$ 9.92

The following table summarizes stock-based compensation expense for employee, director and consultant stock option grants and restricted stock grants:

	Nine Months Ended September 30, 2012 (In thousands)	2013
Stock option expense:		
Employees and directors	\$ 1,138	\$ 3,134
Consultants	113	1,758



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	1,251	4,892
Restricted stock expense:		
Employees and directors		1,315
Consultants		271
		1,586
Total	\$ 1,251	\$ 6,478

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The following table summarizes the activity related to the Company's restricted stock units for the nine month period ended September 30, 2013.

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2012	176,188	\$ 21.23
Granted	24,690	31.90
Vested and converted	(66,309)	21.23
Forfeited		
Outstanding, September 30, 2013	134,569	\$ 23.19

On November 16, 2012 and May 7, 2013, the Company granted to employees and directors restricted stock units ("RSUs") for 173,592 and 24,690 shares of common stock, respectively, under the 2012 Plan. During the three months ended June 30, 2013, the Company issued 36,168 shares of its common stock to settle the vesting of 54,646 RSUs, of which 44,296 RSUs were net settled by withholding 18,478 shares, which represented the employees' minimum statutory obligation for each such employee's applicable income and other employment taxes, and remitted cash totaling \$639,000 to the appropriate tax authorities. The Company does not have a policy for net settlement of RSUs but elected to offer to do this on a one-time basis to its employees for the first vesting of the RSUs on April 9, 2013. The amount remitted for the employees' tax obligation to the tax authorities was reflected as a financing activity within the Company's consolidated statements of cash flows. These shares withheld by the Company as a result of the net settlement of the RSUs are no longer considered issued and outstanding, thereby reducing the Company's shares outstanding used to calculate earnings per share.

**13. Net Loss Per Share**

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

	Three Months Ended September 30, 2012		2013		Nine Months Ended September 30, 2012		2013	
	(In thousands, except share and per share amounts)							
Historical net loss per share								
Numerator:								
Net loss attributable to common stockholders	\$	(6,187)	\$	(31,737)	\$	(15,453)	\$	(55,424)
Denominator:								
Weighted average number of shares of common stock		3,329,266		19,198,923		3,329,266		17,585,531
outstanding, basic and diluted:								

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Net loss per share, basic and diluted	\$ (1.86)	\$ (1.65)	\$ (4.64)	\$ (3.15)
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The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding:

	As of September 30, 2012	2013
	(In thousands)	
Shares issuable upon conversion of preferred stock	7,404	-
Shares issuable pursuant to accumulated preferred stock dividend	1,037	-
Options	1,322	1,535
Warrants to purchase common stock	1,233	878
Restricted stock units	-	135
Total	10,996	2,548

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**14. Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (“FASB”) issued ASU 2013-02, “Comprehensive Income: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.” This accounting standard is an update to existing guidance on the presentation of comprehensive income. This update requires companies to report the effect of significant reclassifications out of accumulated other comprehensive income (AOCI) by component. For significant items reclassified out of AOCI to net income in their entirety during the reporting period, companies must report the effect on the line items in the statement when net income is presented. For significant items not reclassified to net income in their entirety during the period, companies must provide cross references in the notes to other disclosures that already provide information about those amounts. The Company adopted this amendment effective January 1, 2013 and it did not have a material impact on the results of operations or financial position of the Company.

**15. Subsequent Events**

In October 2013, the Company completed a secondary offering of common stock sold by the Company’s two largest stockholders. The selling stockholders, both of which are affiliated with certain of the Company’s directors, sold an aggregate of 1,665,000 shares of common stock in the offering (inclusive of 165,000 shares of common stock from the partial exercise of the option granted to the underwriters to purchase additional shares from the selling stockholders). The Company did not receive any proceeds from the sale of shares by the selling stockholders. The anticipated offering expenses for the secondary offering are approximately \$275,000, which includes legal and accounting costs and various other fees associated with the offering.

In October 2013, the Company entered into a lease agreement to provide the Company with 11,124 rentable square feet (the Primary Space) in New York City for its new corporate headquarters. The rent for the Primary Space (without giving effect to any rent abatements) for the first year will be approximately \$801,000 and will increase by two percent annually until the end of the fifth lease year, at which point the rent will increase to approximately \$940,000 and subsequently increase by two percent annually until July 2024, the termination date. The Company also has a pre-negotiated commitment to take an additional 9,502 rentable square feet (the Additional Space) under a co-terminus lease term expected to commence in September 2014, although the Company may in its sole discretion opt not to take the Additional Space before April 30, 2014 upon the payment of a termination fee of up to approximately \$171,000. The rent for the Additional Space (without giving effect to any rent abatements) for the first year will be approximately \$684,000 and will increase by two percent annually until the end of the fifth lease year, at which point the rent will increase to approximately \$803,000 and subsequently increase by two percent annually until the termination date. The lease requires the Company to provide the landlord with a letter of credit for one year’s annual rent.

In November 2013, the Company entered into an amendment to its collaboration with Servier, together with amendments to its related agreements with Professor Pellicciari and TES, in each case, effective as of October 1, 2013. See Note 3.



## 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 the risk factors set forth in our Annual Report on Form 10-K and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver 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 September 30, 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 \$247.0 million (net of issuance costs of \$14.4 million), including \$29.7 million in net proceeds from our Series C financing in August 2012, \$78.7 million in net proceeds from our initial public offering, or IPO, in October 2012, \$61.2 million of net proceeds from our follow-on public offering in June 2013 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.

On June 24, 2013, we completed a public offering of 1,989,500 shares of our common stock at a price of \$33.01 per share. We received aggregate net proceeds from the offering of approximately \$61.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

We have incurred net losses in each year since our inception in 2002. Our net losses were approximately \$5.2 million and \$31.7 million for the three months ended September 30, 2012 and 2013, respectively, and approximately \$13.0 million and \$55.4 million for the nine months ended September 30, 2012 and 2013, respectively. As of September 30, 2013, we had an accumulated deficit of approximately \$173.6 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs, general and administrative costs associated with our operations and the mark-to-market of our liability-classified warrants.

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

- complete the development of our lead product candidate, obeticholic acid, or OCA, for the treatment of primary biliary cirrhosis, or PBC, and other potential indications;

- 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. On March 15, 2013, we decided to remove our Italian subsidiary from the liquidation process, which removal was completed as of July 15, 2013. 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 Laboratoires Servier and Institut de Recherches Servier, or collectively Servier.

## **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 September 30, 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 September 30, 2013, we recognized \$5.5 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 September 30, 2013, we have incurred approximately \$89.8 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.

	Nine Months Ended September 30, 2012		2013
	(In thousands)		
Direct research and development expense by program:			
OCA	\$	8,084	\$ 10,522
INT-767		-	411
INT-777		38	49
Total direct research and development expense		8,122	10,982
Personnel costs <sup>(1)</sup>		2,763	6,671
Indirect research and development expense		511	705
Total research and development expense	\$	11,396	\$ 18,358

(1) Personnel costs include stock options and RSUs granted to employees and non-employees with an associated stock-based compensation expense of approximately \$497,000 and \$3.4 million for the nine months ended September 30, 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 is 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. As of October 30, 2013, we have enrolled 126 patients into the long-term safety extension phase of our POISE trial.

During 2013 and 2014, we plan to initiate and continue with various nonclinical studies and phase 1 and phase 2 clinical trials and engage various third-party consultants, advisors and vendors to support our planned regulatory submissions for OCA in PBC.

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 approximately \$755,000 and \$3.1 million for the nine months ended September 30, 2012 and 2013, respectively. Other significant general and administrative expenses include costs for director and officer liability insurance, facilities costs, professional fees for directors, accounting, consulting 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 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 other requirements applicable to public companies.

***Other Income and Expense, Net***

Other income and expense, net consists of interest income earned on our cash, cash equivalents and investment securities, offset by capital base, franchise and corporate taxes. We expect interest income to increase in future periods as we invest the proceeds from our preferred stock financings, initial public offering and follow-on public offering.

***Revaluation of Warrants***

In conjunction with various financing transactions prior to our IPO, we issued warrants to purchase shares of our common stock. Certain of the warrants outstanding as of September 30, 2013 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, were recorded as a liability and marked-to-market at each reporting period. Certain warrants outstanding as of September 30, 2013 included a provision that required the shares underlying the warrants to be registered upon the completion of an initial public offering. As a result, these warrants were reclassified as a liability as of the date of our initial public offering and 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.

Warrants to purchase 8,494 shares that contained such provisions expired in October 2013, and the remaining warrants to purchase 865,381 shares will expire in January 2015, if not exercised before the expiration date.

**Results of Operations*****Comparison of the Three Months Ended September 30, 2012 and the Three Months Ended September 30, 2013***

The following table summarizes our results of operations for each of the three months ended September 30, 2012 and 2013, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30, 2012 (In thousands)	2013	Dollar Change	% Change	
Licensing revenue	\$ 523	\$ 405	\$ (118)	(22.6)	%
Operating expenses:					
Research and development	3,318	8,392	5,074	*	
General and administrative	991	3,115	2,124	*	
Loss from operations	(3,786)	(11,102)	(7,316)	*	
Warrant revaluation expense	(1,418)	(20,756)	(19,338)	*	
Other income (expense), net	17	121	104	*	
Net loss	\$ (5,187)	\$ (31,737)	\$ (26,550)	*	

\* Not meaningful or not calculable.

***Licensing Revenue***

Licensing revenue was \$523,000 and \$405,000 for the three months ended September 30, 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 September 30, 2013 is solely related to the amortization of the up-front payment from 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 \$3.3 million and \$8.4 million for the three months ended September 30, 2012 and 2013. The \$5.1 million increase in research and development expense primarily reflects:

- increased stock-based compensation expense of approximately \$1.6 million;
- increased direct development expense for activities around our development program for OCA, including manufacturing of drug supply to support clinical trials of OCA and preparation of the NDA and MAA filings for PBC, of approximately \$4.9 million;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation and benefits expense of approximately \$486,000; and
- increased costs associated with IND enabling studies for INT-767 of approximately \$207,000; partially offset by decreased expenses of \$2.2 million payable by us to the NIDDK relating to milestones under the NIDDK agreement, as all milestones were achieved and paid in 2012. No further milestones are due under this agreement.

***General and Administrative Expenses***

General and administrative expenses were \$991,000 and \$3.1 million in the three months ended September 30, 2012 and 2013, respectively. The \$2.1 million increase primarily reflects:

- increased stock-based compensation expenses of approximately \$898,000;
- increased personnel to manage the increased activities due to our operating as a public company, resulting in increased compensation and benefit expenses of approximately \$236,000;
- increased legal, accounting and security listing expenses of approximately \$125,000 to support our public company operations;
- increased directors' and officers' insurance expense of approximately \$129,000; and
- certain pre-commercial activities related to market research that were not undertaken in the prior year giving rise to expenses of \$741,000.

*Other Income (Expense), Net*

Other income (expense), net was primarily attributable to net interest income earned on cash, cash equivalents and investment securities, which increased by \$132,000 compared to the prior year period as a result of the proceeds from our Series C preferred stock financing in August 2012, our IPO in October 2012 and our follow-on public offering in June 2013. This increase was partially offset by expenses for capital base, franchise and real estate taxes of \$22,000.

*Revaluation of Warrants*

Our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair values of the warrants were determined by us using a Black-Scholes option-pricing model, resulting in the recognition of an expense of \$1.4 million and an expense of \$20.8 million for the three months ended September 30, 2012 and 2013, respectively. These fluctuations in value were primarily due to the increase in the price of the common stock underlying the warrants offset by declines in the estimated life of the warrants and changes in volatility of the shares of 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.

**Results of Operations***Comparison of the Nine Months Ended September 30, 2012 and the Nine Months Ended September 30, 2013*

The following table summarizes our results of operations for each of the nine months ended September 30, 2012 and 2013, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30, 2012 (In thousands)	2013	Dollar Change	% Change	
Licensing revenue	\$ 2,041	\$ 1,216	\$ (825)	(40.0)	%
Operating expenses:					
Research and development	11,396	18,358	6,962	61.1	%
General and administrative	2,994	8,402	5,408	*	
Loss from operations	(12,349)	(25,544)	(13,195)	*	
Warrant revaluation expense	(438)	(30,011)	(29,573)	*	
Other income (expense), net	(165)	131	296	*	
Net loss	\$ (12,952)	\$ (55,424)	\$ (42,472)	*	

\*

Not meaningful or not calculable.

*Licensing Revenue*

Licensing revenue was \$2.0 million and \$1.2 million for the nine months ended September 30, 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 nine months ended September 30, 2013 is solely related to the amortization of the up-front payment from 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 \$11.4 million and \$18.4 million for the nine months ended September 30, 2012 and 2013, respectively, representing an increase of \$7.0 million or 61.1%. This increase in research and development expense primarily reflects:

- increased stock-based compensation expense of approximately \$2.9 million;
- increased direct development expense for activities around our development program for OCA, including manufacturing of drug supply to support clinical trials of OCA and increased preparations of the NDA and MAA



filings for PBC, of approximately \$4.6 million;

an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation and benefits expense of approximately \$1.0 million; and increased costs associated with IND enabling studies for INT-767 of approximately \$410,000; partially offset by decreased expenses of \$2.2 million payable by us to the NIDDK relating to milestones under the NIDDK agreement, as all milestones were achieved and paid in 2012. No further milestones are due under this agreement.

#### *General and Administrative Expenses*

General and administrative expenses were \$3.0 million and \$8.4 million in the nine months ended September 30, 2012 and 2013, respectively. The \$5.4 million increase primarily reflects:

- increased stock-based compensation expenses of approximately \$2.4 million;
- increased personnel to manage the increased activities due to our operating as a public company, resulting in increased compensation and benefit expenses of approximately \$709,000;
- increased legal, accounting and security listing expenses of approximately \$635,000 to support our public company operations;
- increased directors' and officers' insurance expenses of approximately \$395,000; and
- certain pre-commercial activities related to market research that were not undertaken in the prior year giving rise to expenses of \$1.0 million.

### *Other Income (Expense), Net*

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased \$280,000 compared to the prior year period as a result of the proceeds from our Series C preferred stock financing in August 2012, our IPO in October 2012 and our follow-on public offering in June 2013, partially offset by expenses for capital base, franchise and real estate taxes of \$170,000. Other income for the nine months ended September 30, 2012 included a foreign currency loss on liquidation of assets.

### *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 expenses of \$438,000 and \$30.0 million for the nine months ended September 30, 2012 and 2013, respectively. These fluctuations in value were primarily due to the increase in the price of the common stock underlying the warrants offset by declines in the estimated life of the warrants and the changes in volatility of the shares of 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 September 30, 2013 we had an accumulated deficit of approximately \$173.6 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 \$247.0 million (net of issuance costs of \$14.4 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, \$78.7 million in net proceeds from our initial public offering in October 2012, \$61.2 million in net proceeds from our follow-on public offering of common stock in June 2013 and the receipt of \$16.4 million in up-front payments under our licensing and collaboration agreements with DSP and Servier. As of September 30, 2013, we had cash, cash equivalents and investment securities of approximately \$156.8 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 as well as short-term, investment grade, interest bearing instruments such as commercial paper and corporate debt securities and U.S. government securities, 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:

Nine Months Ended	
September 30,	
2012	2013
(In thousands)	

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Net cash provided by (used in):

Operating activities	\$	(11,457)	\$	(17,581)
Investing activities		96		(59,916)
Financing activities		29,632		65,478
Effect of exchange rate changes		(7)		-
Net increase/(decrease) in cash and cash equivalents	\$	18,264	\$	(12,020)

*Operating Activities.* Net cash used in operating activities of \$11.5 million during the nine months ended September 30, 2012 was primarily a result of our \$13.0 million net loss and net changes in operating assets and liabilities of \$564,000, partially offset by non-cash items consisting of \$1.3 million for stock-based compensation, warrant liability revaluation of \$438,000 and depreciation and amortization of \$178,000. Net cash used in operating activities of \$17.6 million during the nine months ended September 30, 2013 was primarily a result of our \$55.4 million net loss and net changes in operating assets and liabilities of \$198,000, partially offset by non-cash items consisting of \$30.0 million of expense for warrant liability revaluation, \$6.5 million for stock-based compensation, \$1.1 million for amortization of investment premiums and \$79,000 for depreciation.

*Investing Activities.* Net cash used in investing activities during the nine months ended September 30, 2013 was primarily related to the purchase of short-term investments of \$86.2 million, partially offset by the sale of short-term investments of \$26.4 million.

*Financing Activities.* Net cash from financing activities of \$65.5 million for the nine months ended September 30, 2013 reflects the net proceeds of \$61.2 million from the issuance of common stock in our follow-on public offering in June 2013 and the proceeds from the exercise of stock options of \$4.3 million net of amounts remitted to tax authorities in relation to the net share settlement of employee RSUs that vested during the period.

### **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 pre-commercialization and 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, and short-term investments as of September 30, 2013 of \$156.8 million and anticipated funding under our collaborations will enable us to fund our operating expenses and capital expenditure requirements through early 2016. This estimate reflects our ongoing POISE trial and long-term safety extension of the POISE trial; nonclinical studies and clinical trials and consulting expenditures to support our planned regulatory submissions for OCA in PBC; anticipated pre-commercial activities for OCA in PBC; and IND-enabling studies of INT-767. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

- the results of our POISE trial;
- 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 clinical development of OCA for other potential indications;
- 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 qualified management, scientific and medical, commercial and other 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.

On October 15, 2013, we entered into a lease agreement with Jamestown 450 West 15th Street, L.P. for our new corporate headquarters in New York City. The lease will provide us initially with 11,124 rentable square feet, or the Primary Space, in New York City for corporate and administrative use. We also have a pre-negotiated commitment to take an additional 9,502 rentable square feet, or the Additional Space, under a co-terminus lease term expected to commence in September 2014, although we may in our sole discretion opt not to take the Additional Space before April 30, 2014 upon the payment of a termination fee of up to approximately \$171,000. The term of the new lease will expire in July 2024 with an aggregate minimum lease commitment over the term of approximately \$10.1 million.

The rent for the Primary Space (without giving effect to any rent abatements) for the first year will be approximately \$801,000 and will increase by two percent annually until the end of the fifth lease year, at which point the rent will increase to approximately \$940,000 and subsequently increase by two percent annually until the termination date. The rent for the Additional Space (without giving effect to any rent abatements) for the first year will be approximately \$684,000 and will increase by two percent annually until the end of the fifth lease year, at which point the rent will increase to approximately \$803,000 and subsequently increase by two percent annually until the termination date. We are entitled to receive nine months and eight months of rent abatement for the Primary Space and the Additional Space, respectively. This lease incentive liability will be amortized as rent expense on a straight-line basis over the term of the lease. The landlord has also agreed to provide us with contributions for improvements of up to approximately \$667,000 and approximately \$570,000 for the Primary Space and the Additional Space, respectively. The lease contains customary provisions relating to default, termination and other events that may lead to a suspension of the parties’ obligations. The lease for our current New York City headquarters will expire in November 2013, and we are currently negotiating a short-term extension with the landlord.

The October 2013 lease requires us to provide the landlord with a letter of credit for \$801,000 and \$684,000 for the Primary Space and the Additional Space, respectively, as of the commencement date of the lease for such space. We will be permitted to decrease the letter of credit amount at certain times over the duration of the lease.

In November 2013, we entered into Amendment No. 4 to Product Research, Development, License and Commercialization Agreement with Servier. The amendment, which became effective as of October 1, 2013, among other matters, extended the term of our research program with Servier relating to the discovery of novel TGR5 agonists, or the Servier TGR5 Agonists, until September 30, 2015. The research program was extended on the same financial terms as were previously in effect, including the reimbursement by Servier of the full time equivalent costs incurred by us in the conduct of the research program, up to a set maximum amount.

Concurrently, we also entered into amendments to our consulting agreement with Professor Pellicciari and our research agreement with TES Pharma Srl, or TES, in each case, for the Servier TGR5 Agonists. These amendments,

which became effective as of October 1, 2013, among other matters, extended the term of services provided by Professor Pellicciari and TES in relation to the research program for the Servier TGR5 Agonists until September 30, 2015. The consulting agreement with Professor Pellicciari was extended on the same financial terms as were previously in effect. Pursuant to our amended agreement with TES, we are required to pay TES an aggregate amount of €250,000 on a quarterly basis during the extended term. We also agreed to provide TES with a low single digit royalty based on worldwide net sales of products developed under the agreement on a country-by-country basis. Royalty rates are subject to reduction under the agreement in specified circumstances, including with respect to any country if sales of generic products reach a certain threshold in that country.

### **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 September 30, 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.**

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 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in such filings.

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

**Recent Sales of Unregistered Securities**

Set forth below is information regarding securities sold by us during the nine months ended September 30, 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 September 30, 2013, we issued an aggregate of 231,568 shares of common stock upon exercise of previously issued and outstanding warrants to purchase common stock. All such shares, except for 2,803 shares that were issued upon the cash exercise of a warrant, 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 September 30, 2013, the net proceeds from our initial public 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.**

None.

**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: November 14, 2013

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

Date: November 14, 2013

By: /s/ Barbara Duncan  
Barbara Duncan  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

## Exhibit Index

Exhibit Number	Description of Exhibit
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 September 30, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2012 and September 30, 2013 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month and nine month periods ended September 30, 2012 and 2013 (unaudited), and the period from September 4, 2002 (inception) through September 30, 2013 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2012 and 2013 (unaudited) and for the period from September 4, 2002 (inception) to September 30, 2013 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited).+
+	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.